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. **No more certificates needed with SynchroMed™ II.** That is because Medtronic invested and successfully navigated through the consent decree deliverables to ensure patients continue to receive the therapy

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]

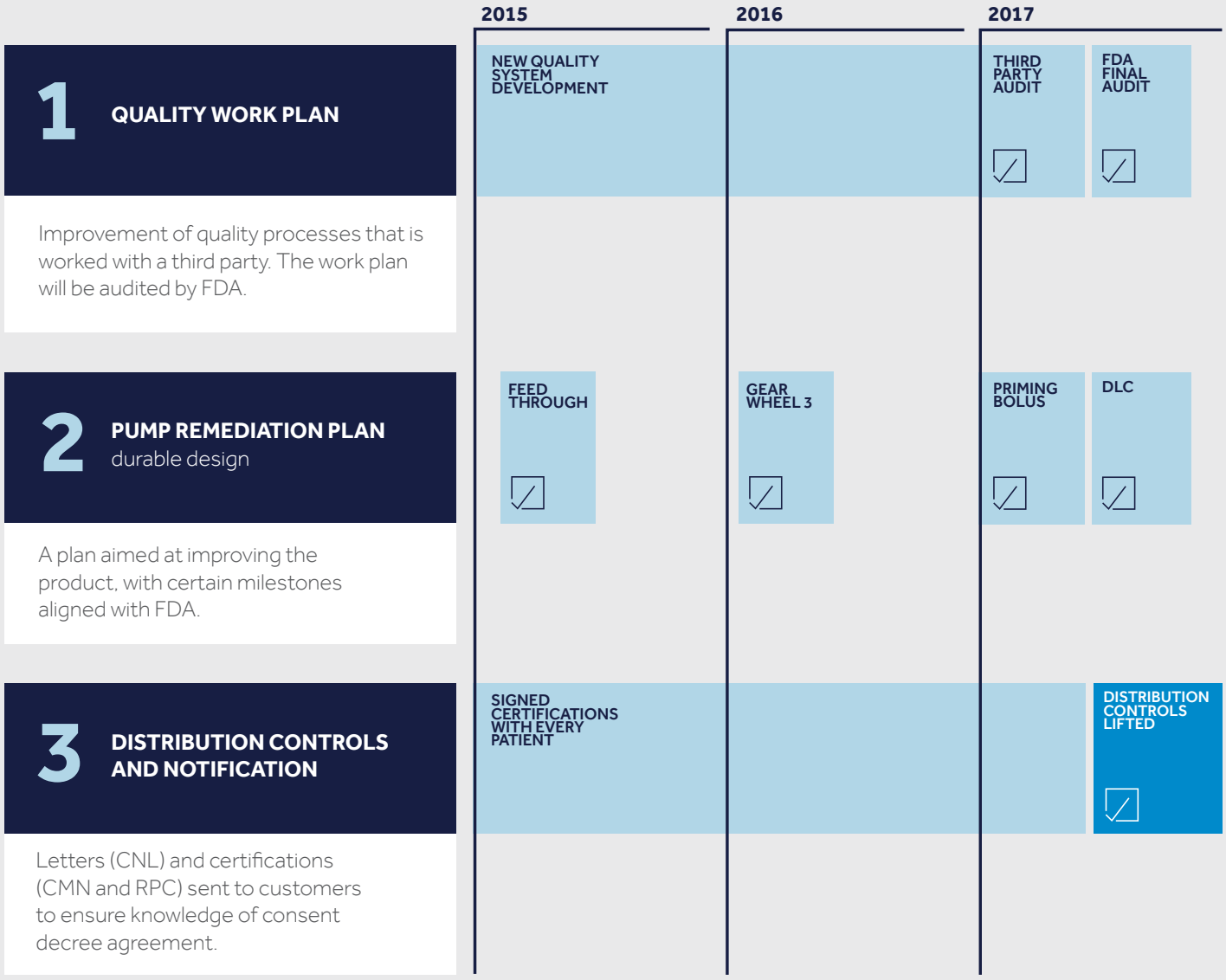
[1] Based on all pumps returned and analyzed for motorstalls

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

NO MORE CERTIFICATES WITH SYNCHROMED™ II IMPLANTS

That is because Medtronic invested and successfully navigated through the consent decree* deliverables to ensure patients continue to receive the therapy. Medtronic delivered on all FDA expectations in regards to a quality work plan and product enhancements, which enabled us to exit the certification process.

This means that you do not need to sign any certificates for your SynchroMed™ II implants anymore.



* Consent decree is a formal agreement with the FDA to address its expectations in regards to: (a) SynchroMed™ II and; (b) overall neuromodulation quality system. It gives the FDA greater oversight of our existing quality improvement efforts and provides a path forward with steps and timelines (three pillars, quality work plan, pump remediation plan and distribution controls/notification of associated persons).

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