

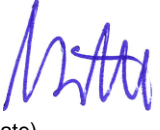




F17-2014	test report Lifecycle MMN		 <small>Medizin-Mechanik-Nord GmbH</small> <small>zertifiziert nach:</small> <small>DIN EN ISO 9001</small> <small>DIN EN ISO 13485</small>	
Anhang A: Timeline				
Anhang B: visual documentation				
Anhang C: measurement series				
project name:	Self-retaining Screwdriver Torx T15		Projekt No.:	4179- 051201
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1. Introduction:

In 2005, Medizin-Mechanik-Nord GmbH developed and patented a self-retaining screwdriver system. Patent No.: PCT/DE 2006 001185. As part of a collaboration with Stryker, the self-retaining screwdriver developed by Medizin-Mechanik-Nord GmbH was adapted to Stryker's design specifications (e.g., fixed silicone handle). Stryker successfully conducted life cycle tests in 2006. The product for Stryker has been in series production at MMN since 2006 and is marketed by Stryker. MMN is FDA-registered with this product.

For its own design of the self-holding screwdriver, MMN has replaced the existing silicone handle with a Small AO connector, thereby eliminating the risk associated with possible detachment of the silicone..



Fig.1 Blade T15 with AO connection **Fig.2** Sleeve T15



Fig. 3 Self-retaining screwdriver with AO connection + screw

From August 19, 2014, to September 8, 2014, six samples from Medizin-Mechanik-Nord GmbH were tested for functionality, corrosion, tightness, service life, and wear.

The following acceptance criteria for the lifecycle test series were defined by Medizin-Mechanik-Nord GmbH:

- Sterilization cycles: 500 cycles
- Applications * 2.000
- Wash cycles: 25 cycles
- Corrosion: not permitted
- Housing tightness: guarantee

*Applications:

- Attaching the screw
- Turn the torque limiter until it releases (click).
- Screw in, screw out
- Release torque limiter
- Remove screw
- Test axial pull-off force with weight

limit values:

screwdriver Typ	Limit values Test start		Limit values Lifetime	
	suction force / N	Slip clutch release torque	suction force / N	Slip clutch release torque
T15	≥30	0,3 +/-0,1	≥20	0,15 +0,25
T20	≥50	0,3 +/-0,1	≥20	0,15 +0,25
T25	≥50	0,3 +/-0,1	≥20	0,15 +0,25
SW2,5	≥30	0,3 +/-0,1	≥20	0,15 +0,25
SW3,5	≥50	0,5 +/-0,1	≥20	0,35 +0,25

2. Experimental setup

Stryker equivalent test setups were used as the basis for conducting the lifecycle test series.

The test machines are listed in Table 1 and described below with their parameters and characteristics.

table 1

No..	designation	Typ
1	Sterilizer	Systec Autoclave DX 65
2	washing machine	Miele G7735
3	Torque tester	Stahlwille Sensotork 7707-1W
4	Weight for pull-off force	50N (5 Kg)
5	Weight for pull-off force	30N (3 Kg)
6	Weight for pull-off force	20N (2 Kg)

Test setup parameters / properties:

Re No. 1: sterilization temperature: 137°C,
steam application: 3 bar mit VE Wasser,
holding time: 7 min.
spray cooling: Fully desalinated water,
duration: approx. 45 min.



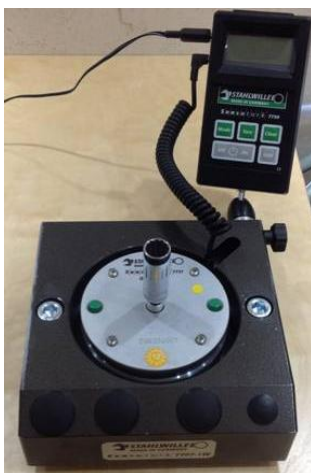
Re No. 2: temperature:
cleaning agent:
flushing:
duration:
washing program:

40°C / 95°C,
Neodisher MediZym Dr. Weigert
with fully desalinated water,
approx. 60 min.
G7736 Washing without neutralization



Re No. 3: digital display 7750
measuring cell 7721:
connection:
measurement mode:

0,2 - 10,0 Nm (Art. Nr.: 506334067)
AO blade adapter
Peek Hold



Re No. 4: Gewicht für Abzugskraft 50N (5,0 Kg)



Nos. 5 and 6 not shown.

2. Performing lifecycle testing

The samples were constructed identically and labeled numerically. Under the specified test parameters, the six samples underwent the following test:

10 Trigger torque measurements
400 Applications*
100 sterilization cycles
Washing cycles sporadic

* Applications:

- Attaching the screw
- Turn the torque limiter until it releases (click).
- Test axial pull-off force with weight
- Screw in, screw out
- Release torque limiter
- Remove screw

The samples underwent this test cycle a total of 5 times, resulting in 500 sterilization cycles, 2,000 applications, and 25 wash cycles.

– *Appendix A.*

3. Measured values and graphical representation

The tables in Appendix C contain the following data: Sample No., measured values for trigger torque 1-10, maximum value, minimum value.

The table values were then plotted in a graph in Appendix C.

The measurements of the axial pull-off force were verified using weights (No. 4, No. 5, and No. 6).

3. Analysis of the measured values

For each sample, the progression of the trigger moments over the entire lifecycle was represented in a graph. The six graphs were compared and analyzed with each other—see *Appendix C*.

- After each sterilization cycle, there is a slight increase in torque, which is within the limits predefined in Table 1 for all samples.
- The axial pull-off force for all samples is within the limits specified in Table 1
- The washing cycles did not result in any significant change in the behavior of the samples.
- The 6 samples showed no deviations from the specifications throughout the entire lifecycle test.

The evaluation of the graphs showed that all samples exhibited the same behavior throughout the entire lifecycle test series. All samples met the specifications of the lifecycle test.

3. Disassembly and evaluation

After completion of the lifecycle cycles, the torque limiters of the samples were opened at the rear, dismantled, and the results documented..

The samples were examined according to the following criteria – See *Appendix B* for more information.:

- Corrosion on individual components
- Moisture in the housing
 - Signs of wear on the interacting individual components
- Cracking/fracturing of components

4. Final remarks

The six samples of the "T15 self-retaining screwdriver" tested in the life cycle test series from August 19 to September 8, 2014 demonstrated full functionality..

All required limits are complied with.

The functionality of the samples is also unaffected in terms of the AO connection mechanism and torque release behavior.

There are no cracks in the weld seams or corrosion on the outer casing of the torque limiters and the moving components.

After opening the samples, no moisture or corrosion was detected inside the housings.

No cracks, breaks, or corrosion were visible on the internal components.

Minimal signs of wear are visible on the interacting individual components, but these do not impair the function of the system..

Finally, the test results show that the screwdriver systems tested meet the specified requirements.