



Neodent GM Guided Surgery Overview

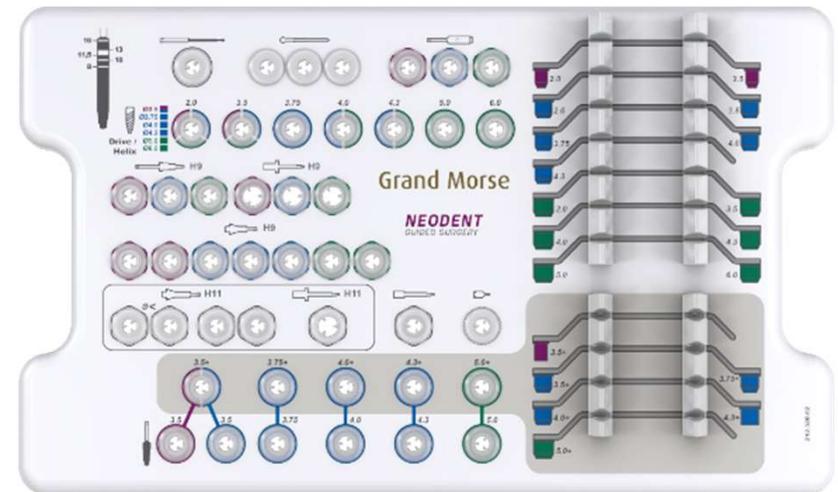
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Internal Use Only

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The clearance of the tray for GM Guided Surgery is expected in April/May of 2019

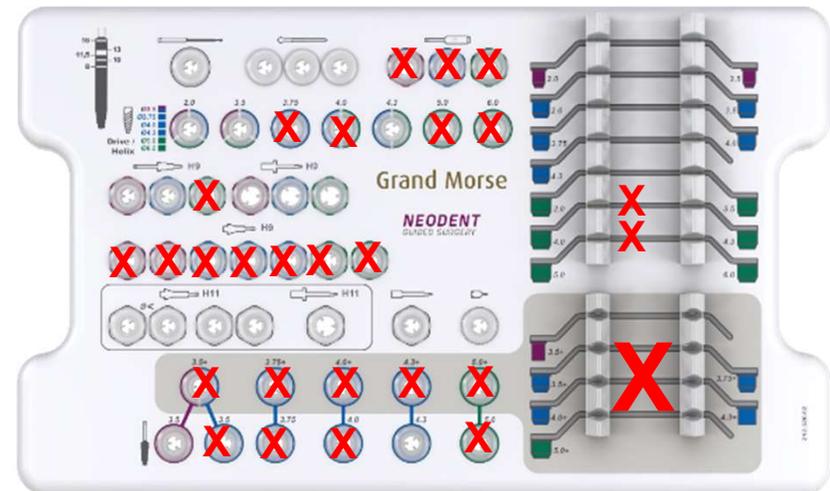
- Due to the extended clearance time for the GM NGS cassette a work around has been developed
 - The plastic cassette is now considered a medical device and requires the same rigorous testing that is required of other medical devices
- All of the GM GS tools have already been released
- In the interim while this kit is being cleared, we will utilize the CM Alvim/Drive Compact CM GS Kit



*The GM NGS surgical cassette is pending 510K clearance.

GM Guided Surgery Kit workaround will be the CM Compact GS Kit

- The CM Compact GS Kit is used to place the CM Drive and Alvim implants
- It contains the same base drills that the GM GC kit will use for GM Drive and Helix Implants
- The CM GS Compact Kit can be used as a substitute until the GM GS Kit is cleared but there are limitations to the size of the kit and the items contained in it
 - 56 articles in the GM Kit- There are 27 articles in the CM GS Compact kit
 - The CM GS kit has spots for drills up to a 4.3- 5.0 and 6.0 drills do not have spots
 - There are no spots for the Tapered Contour drills and spoons to place the Helix in Type I and II bone
 - No spots for tissue punches
 - Two spots for the Pilot drills are not available

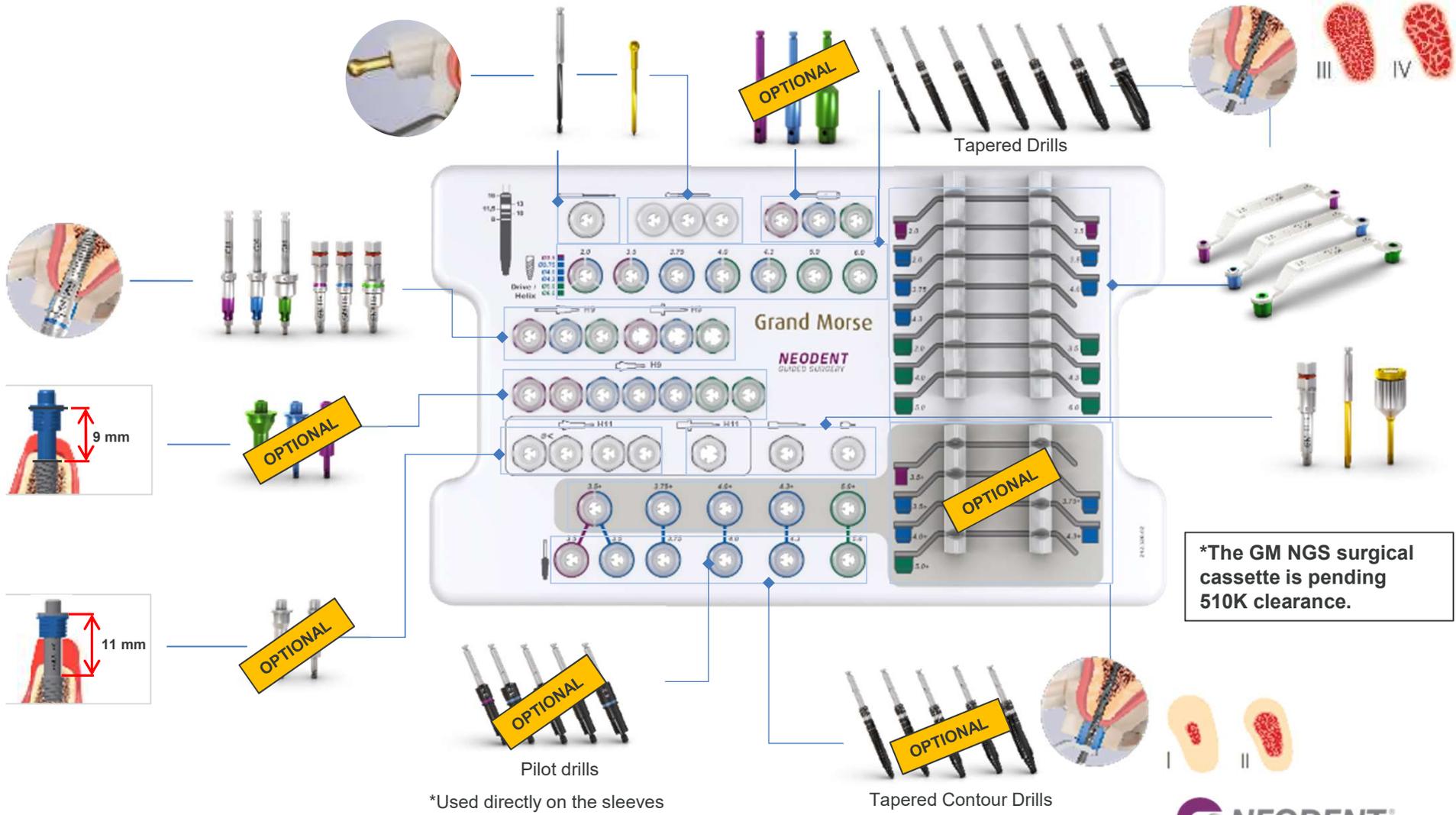


X = No spot for this item in the CM Compact GS Kit

***The GM NGS surgical cassette is pending 510K clearance.**



Within the GM NGS Kit there are a number of the tools that we can exclude from the kit



*Used directly on the sleeves

A number of the tools within the GM NGS Kit will not be included due to space reasons

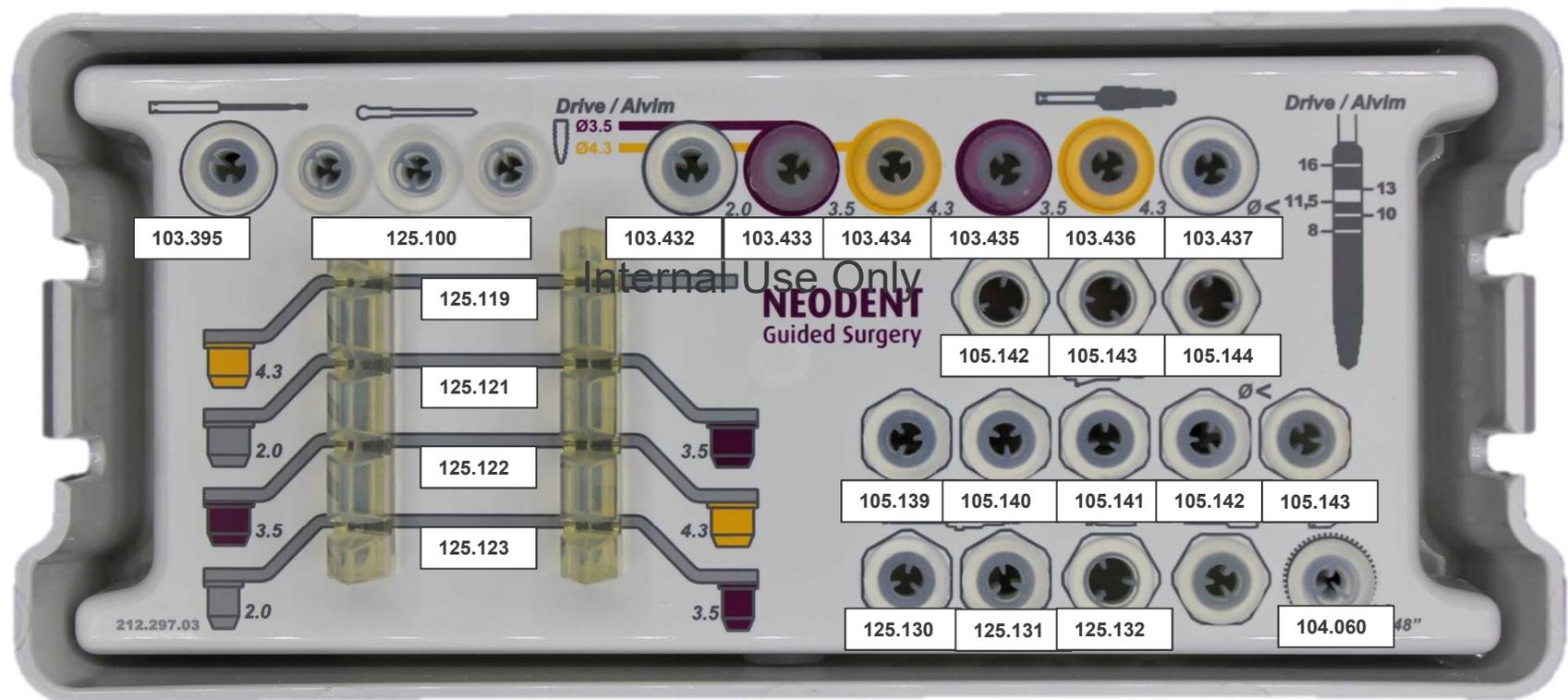
- The following articles have pulled out of the GM interim configuration
- These items are not required for accomplishing a guided surgery case

Material	Description	Status	Position	Quantity
103.438	Tapered Guided Surgery Drill 6.0	Optional		
103.449	Guided Surgery GM Pilot Drill 5.0	Optional		
103.439	Tapered Contour Guided Surgery Drill 3.5	Optional		
103.440	Tapered Contour Guided Surgery Drill 3.75	Optional		
103.441	Tapered Contour Guided Surgery Drill 4.0	Optional		
103.442	Tapered Contour Guided Surgery Drill 4.3	Optional		
103.443	Tapered Contour Guided Surgery Drill 5.0	Optional		
103.444	Narrow Guided Surgery GM Pilot Drill 3.5	Optional		
103.445	Regular Guided Surgery GM Pilot Drill 3.5	Optional		
103.446	Guided Surgery GM Pilot Drill 3.75	Optional		
103.447	Guided Surgery GM Pilot Drill 4.0	Optional		
103.448	Guided Surgery GM Pilot Drill 4.3	Optional		
103.429	Narrow Guided Surgery Mucosa Punch	Optional		
103.430	Regular Guided Surgery Mucosa Punch	Optional		
103.431	Wide Guided Surgery Mucosa Punch	Optional		
125.120	Narrow Tapered Contour Guided Surgery Drill Guide 3.5	Optional		
125.124	Regular Tapered Contour Guided Surgery Drill Guide 3.5/3.75	Optional		
125.125	Regular Tapered Contour Guided Surgery Drill Guide 4.0/4.3	Optional		
125.129	Wide Tapered Contour Guided Surgery Drill Guide 5.0	Optional		
105.145	H11 Guided Surgery GM Connection - Torque Wrench	Optional		
125.133	Narrow Guided Surgery GM Guide Stabilizer - Long	Optional		
125.134	Regular Guided Surgery GM Guide Stabilizer - Long	Optional		

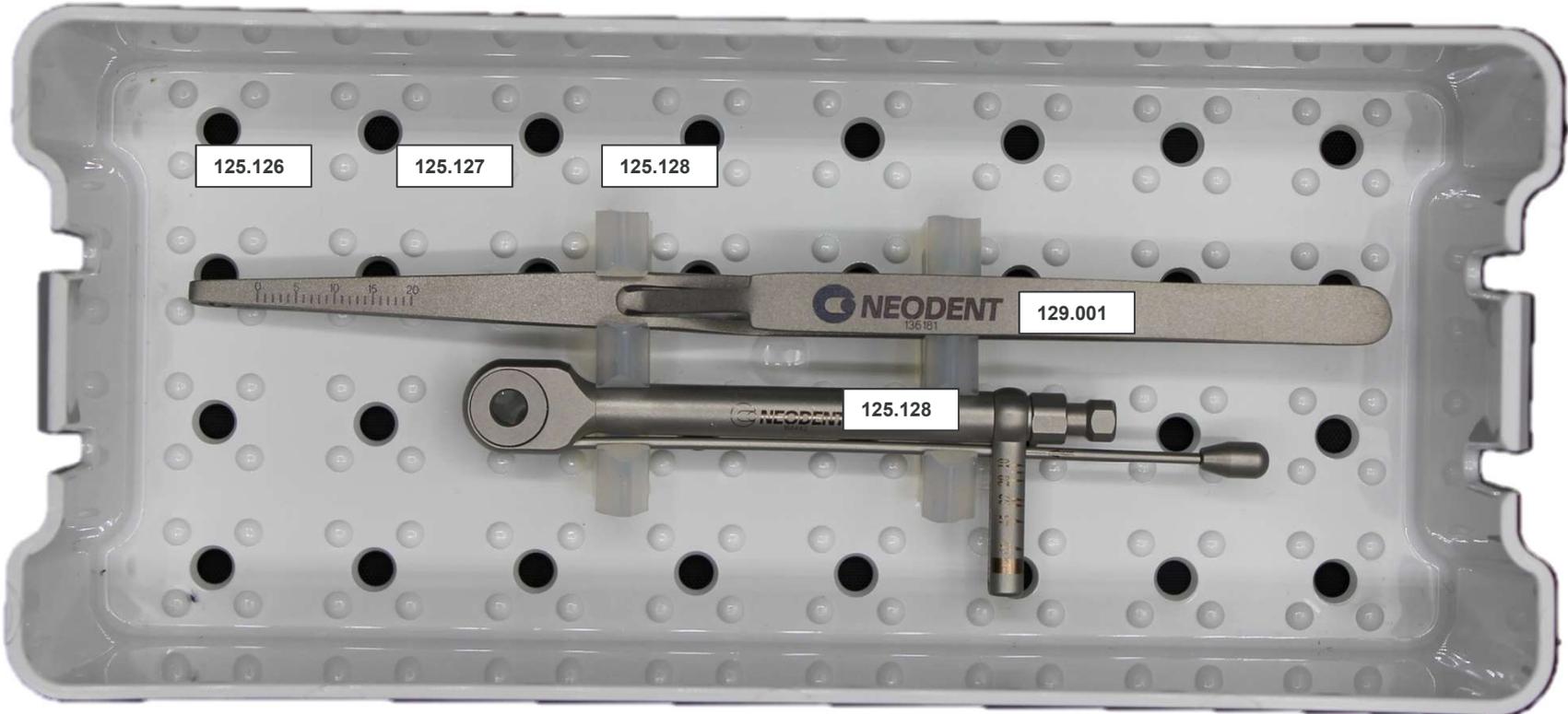
The interim GM NGS Kit will include the following tools

Material	Description	Status	Position	Quantity
105.144	Wide Guided Surgery GM Connection - Torque Wrench			1
125.100	Guided Surgery guide Clamp			3
103.395	Guided Surgery Drill 1.3			1
103.432	Guided Surgery Drill 2.0			1
103.433	Tapered Guided Surgery Drill 3.5			1
103.434	Tapered Guided Surgery Drill 3.75			1
103.435	Tapered Guided Surgery Drill 4.0			1
103.436	Tapered Guided Surgery Drill 4.3			1
103.437	Tapered Guided Surgery Drill 5.0			1
125.119	Narrow Guided Surgery Drill Guide 2.0/3.5			1
125.121	Regular Guided Surgery Drill Guide 2.0/3.5			1
125.122	Regular Guided Surgery Drill Guide 3.75/4.0			1
125.123	Regular Guided Surgery Drill Guide 4.3			1
125.126	Wide Guided Surgery Drill Guide 2.0/3.5		Bottom of tray	1
125.127	Wide Guided Surgery Drill Guide 4.0/4.3		Bottom of tray	1
125.128	Wide Guided Surgery Drill Guide 5.0/6.0		Bottom of tray	1
105.139	Narrow Guided Surgery GM Connection - Contra-angle			1
105.140	Regular Guided Surgery GM Connection - Contra-angle			1
105.141	Wide Guided Surgery GM Connection - Contra-angle			1
105.142	Narrow Guided Surgery GM Connection - Torque Wrench			1
105.143	Regular Guided Surgery GM Connection - Torque Wrench			1
125.130	Narrow Guided Surgery GM Guide Stabilizer			1
125.131	Regular Guided Surgery GM Guide Stabilizer			1
125.132	Wide Guided Surgery GM Guide Stabilizer			1
104.060	Neo Manual Screwdriver - Medium			1
129.001	Titanium Tweezers		Bottom of tray	1
104.050	Torque Wrench		Bottom of tray	1

Here is the proposed layout of the CM GS Kit for the new GM GS tools



Bottom of Kit





Thank you

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