

Tray Assembling/Sanitation/Reuse Guide

Helix™ GM Compact Surgical Kit



COMPONENTS LIST

-	110.297	Helix GM Compact Surgical Kit Case
1	103.170	Initial Drill
2	103.425	Tapered Drill 2.0
3	103.561	Tapered Drill 3.5
4	103.564	Tapered Drill 3.75
5	103.567	Tapered Drill 4.0
6	103.570	Tapered Drill 4.3
7	103.573	Tapered Drill 5.0
8	103.576	Tapered Drill 6.0
9	103.577	Tapered Drill 7.0
10	104.060	Neo Manual Screwdriver Medium
11	104.028	Manual Implant Driver - Contra-Angle
12	103.426	Drill Extension
13	103.578	Tapered Contour Drill 3.5
14	103.579	Tapered Contour Drill 3.75
15	103.580	Tapered Contour Drill 4.0
16	103.581	Tapered Contour Drill 4.3
17	103.582	Tapered Contour Drill 5.0

18	105.168	GM Implant Driver - Contra-Angle
19	105.130	GM Implant Driver - Torque Wrench Long
20	105.129	GM Implant Driver - Torque Wrench Short
21	103.513	GM Pilot Drill 2.8/3.5
22	103.514	GM Pilot Drill 3.0/3.75
23	103.515	GM Pilot Drill 3.3/4.0
24	103.516	GM Pilot Drill 4.3
25	103.517	GM Pilot Drill 4.3/5.0
26	128.028	GM Height Measurer
27	128.030	Angle Measurer 17° - For Drill 2.0
28	128.031	Angle Measurer 30° - For Drill 2.0
29	128.019	Direction Indicator 2.8/3.5
30	128.020	Direction Indicator 3.0/3.75
31	128.021	Direction Indicator 3.3/4.0
32	128.022	Direction Indicator 3.6/4.3
33	128.023	Direction Indicator 4.3/5.0
34	129.004	Depth Probe
35	104.050	Torque Wrench

*Tapered Drill 7.0 is not included in the pre-mounted kit composition (110.303).

TORQUE WRENCH ASSEMBLING



ASSEMBLY:

1. Fit the gear into the compartment found on the Torque Wrench body. Make sure that the gear is inserted through its lower part.
2. Insert the axis in the orifice and screw it until the perfect fitting is achieved.

DISASSEMBLY:

1. Remove the axis.
2. Remove the gear.

REMINDER: the torque wrench must be disassembled for the sterilization stage.

SANITATION

This product must be correctly cleaned after each use. Proceed as follows:

MANUAL CLEANING AND DISINFECTION

Cleaning

1. Disassemble the instruments if possible (see specific disassemble instructions for each instrument, when applicable).
2. Soak the disassembled instruments for at least 1 minute in the cleaning solution (CIDEZYME®, 1.6 % v/v) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by carefully brushing with a soft brush. Sway movable parts several times during cleaning. If applicable, rinse all lumens of the instruments for, at least, five times using a single-use syringe (minimum volume of 10 mL) and of a suitable rinsing adapter.

3. Soak the disassembled instruments for 15 minutes in the cleaning solution (CIDEZYME®, 1.6% v/v) with ultrasonic treatment so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments.
4. Remove the instruments from the cleaning solution and intensively post-rinse them for, at least, 3 times (for the minimum time of 1 minute) under running water. If applicable, rinse all lumens of the instruments for, at least, five times at the beginning of the soaking time using a single-use syringe (minimum volume of 10 mL) and of a suitable rinsing adapter.

Disinfection

1. Soak the disassembled instruments for 12 minutes in the disinfectant solution (CIDEX® OPA - OPA Solution -, undiluted) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Sway movable parts several times during disinfection. If applicable, rinse all lumens of the instruments for, at least, five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume of 10 mL) and of a suitable rinsing adapter.

- Solution - Solution, thoroughly rinse the medical device by immersing it completely in a large volume of water. Use sterile water unless potable water is acceptable (maximum of 10 germs/mL, maximum of 0.25 endotoxin/mL).
- Keep the device totally immersed for, at least, 1 minute.
 - Manually flush all lumens with large volumes (not less than 100 mL) of rinse water.
 - Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
 - Repeat the procedure for 2 additional times, concluding A TOTAL OF 3 RINSES, with large volumes of fresh water to remove CIDEX® OPA - OPA Solution - solution residues. Residues may cause serious side effects.

2. Remove the instruments from the disinfectant solution and post-rinse them according to the instructions of the manufacturer of CIDEX® OPA - OPA Solution-:

Rinsing Instructions

- Following removal of the instruments from CIDEX® OPA - OPA

3. Check and pack the instruments immediately after the removal.

AUTOMATED CLEANING/DISINFECTION (WD (WASHER-DISINFECTOR))

Use neodisher® MediZym.

1. Disassemble the instruments if possible (see specific disassemble instructions for each instrument, when applicable).
2. Transfer the disassembled instruments to the WD (pay attention that the instruments are not in contact with each other).
3. Start the program.

4. Remove the instruments from the WD after the end of the program.
5. Check and pack the instruments immediately after the removal.

NOTE:

1. Pay attention to the following points during the selection of the WD:
- approved efficiency of the WD (e.g. CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration);

• possibility of an approved program for thermal disinfection (AO value > 3000 or – in case of older devices - at least 5 minutes at 90 °C/194 °F; in case of dangerous chemical disinfection of disinfectant remnants on the instruments);

• use appropriate program for instruments, as well as sufficient information on rinsing in the program;

• post-rinsing only with sterile or low contaminated water (e.g. maximum of 10 germs/mL, maximum of 0.25 endotoxin/mL); for example purified/highly purified water;

• use only filtered air (oil-free, low contamination with microorganisms and particles) for drying;

• regular maintenance and check/calibration of the WD.
2. Please do not clean any instruments using metal brushes or steel wool.
3. After cleaning and disinfection, check all instruments on corrosion, damaged surfaces, and impurities. Do not use damaged instruments. Instruments that are still contaminated must be cleaned and disinfected again.
4. Packaging: insert the cleaned and disinfected instruments on the corresponding sterilization trays and pack them, in single-use sterilization packagings (single or double packaging) and/or sterilization containers, which fulfill the following requirements:
- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance);

- suitable for steam sterilization;
- sufficient protection for instruments as well as for maintenance of sterilization packagings against mechanical damage;
5. After using the instruments, it is recommended to remove coarse impurities, performing the pre-treatment, before cleaning and disinfection (within a maximum deadline of 2 hours).
- Regular maintenance according to the instructions of the manufacturer (sterilization container).
- The pre-treatment step must be performed for both cases of cleaning and disinfection (automated and manual).
- a. Disassemble the instruments if possible;
- b. Rinse the instruments for, at least, 1 minute under running water (temperature <35 °C/95 degrees F);
- c. If applicable, rinse all lumens of the instruments five times per application using a single-use syringe (minimum volume of 10 mL). Sway movable parts several times during pre-treatment;
- d. Remove manually all visible impurities by using a clean and soft brush (or a clean, soft, and lint-free cloth). In no case use metal brushes or steel wool;
- e. Rinse again for, at least, 1 minute under running water.
6. If the cleaning/disinfection products mentioned cannot be found, make sure to use similar products to those indicated. This replacement is the owner's responsibility.
7. The drying of the parts is of utmost importance before storage and sterilization, because the accumulation of moisture on the products is harmful and may cause oxidation.

PRESENTATION AND STERILIZATION

For traceability, each cassette presents on its tray the laser engraving of the UDI code (Unique Device Identification). This product is reusable and supplied non-sterile, being unitarily packaged. This product must be correctly sanitized and sterilized before each use. Sterilize the products on the day before or on the day of the procedure.

ATTENTION: This product cannot be autoclaved in its original packaging. Please use for sterilization only the steam sterilization according to the following parameters:

	Fractionated Vacuum / Dynamic Air Removal ¹	Gravity Displacement ²
Sterilization Time	4 minutes	15 minutes
Sterilization Temperature ³	132°C/270°F	132°C/270°F
Drying Time	At least 20 minutes ⁴	At least 20 minutes ⁴

¹ At least three vacuum steps.

² The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure.

³ Maximum sterilization temperature 134°C (273°F)

⁴ The effectiveness required in drying time depends directly on the parameters of sole responsibility of the user (density and load configuration, sterilizing conditions, which must be determined by the user). Nevertheless, a drying time shorter than 20 minutes cannot be applied.

NOTE: 1. Please store the instruments after sterilization in the sterilization packagings at a dry and dust-free place.






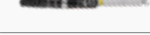





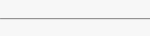

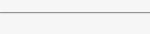

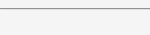




2. The flash/immediate use sterilization procedure must not be used.

3. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

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SURGERY TRACKING SHEET FOR REUSABLE INSTRUMENTS

Neodent® Helix™ GM Drills and Torque Wrench are recommended for up to 30 uses, as long as the conditions of use indicated by Neodent® are respected. Regardless of the amount of times that the instrument has been used, the professional must always evaluate its condition after each use. For further information, please refer to each product's Instruction for Use, available at ifu.neodent.com.br.

IMAGE	ARTICLE	DESCRIPTION	DIAMETER mm	LENGTH mm	NUMBER OF SURGICAL PROCEDURES
	103.170	Initial Drill	2.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.425	Tapered Drill 2.0	2.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.561	Tapered Drill 3.5	3.5	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.564	Tapered Drill 3.75	3.75	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.567	Tapered Drill 4.0	4.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.570	Tapered Drill 4.3	4.3	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.573	Tapered Drill 5.0	5.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.576	Tapered Drill 6.0	6.0	31	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.577	Tapered Drill 7.0*	7.0	31	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.578	Tapered Contour Drill 3.5	3.5	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.579	Tapered Contour Drill 3.75	3.75	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.580	Tapered Contour Drill 4.0	4.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.581	Tapered Contour Drill 4.3	4.3	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.582	Tapered Contour Drill 5.0	5.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.513	GM Pilot Drill 2.8/3.5	3.5	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.514	GM Pilot Drill 3.0/3.75	3.75	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.515	GM Pilot Drill 3.3/4.0	4.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.516	GM Pilot Drill 4.3	4.3	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	103.517	GM Pilot Drill 4.3/5.0	5.0	35	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
	104.050	Troque Wrench**	-	-	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30

*Tapered Drill 7.0 is not included in the pre-mounted kit composition [110.303].

**The torque wrench must be disassembled for the sterilization stage.