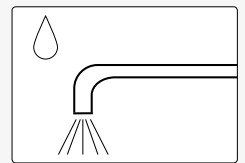


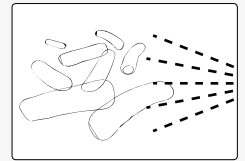
Processing of Instruments



cleaning



disinfection



sterilization

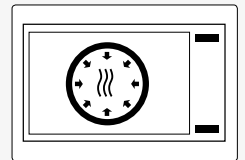




















Figure: SKYOT100 from breident medical

Processing of Instruments

Symbol	Title of Symbol	Description of symbol
	European conformity marking	The CE marking symbolizes the conformity of the product with the applicable requirements that the European Community places on the manufacturer.
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
Rx only	Prescription only	Caution: Federal law restricts this device to sale by or on the order of a dentist.

This instruction "Processing of instruments" reflect the current state of the Validation. With the publication of this instruction, all previous versions lose their validity.

All names marked with ® or ™ are protected brands and/or company names of third-party rights holders.

All products labelled with the symbol  are solely intended for single use. However, if this product is used multiple times, the following risks can occur: cross-contamination, malfunction, inaccuracies of fit, etc.

CONTENT

1.	<u>Fundamental points</u>	4
2.	<u>Cleaning and disinfection</u>	5
2.1	Basic Information	5
2.2	Pre-treatment	6
2.3	Automated cleaning/disinfection (WD [Washer-Disinfector])	8
3.	<u>Check</u>	10
4.	<u>Maintenance</u>	11
5.	<u>Packaging</u>	12
6.	<u>Sterilization</u>	13
7.	<u>Storage</u>	14
8.	<u>Material resistance</u>	15
9.	<u>Reusability</u>	16
10.	<u>Specific aspects</u>	17
10.1	Trays	17
10.2	Torque wrench and accessories	18
10.3	Depth stops	19
10.4	Mounter	20
10.5	Screwdriver	22
10.6	SKY drills	24
10.7	SKYplanX drills	25
10.8	Figures	26

Processing of Instruments

1. Fundamental points

All instruments are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure

- that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization,
- that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as
- that the validated parameters will be applied for each cycle.

Please pay attention to avoid a higher contamination of the complete insert/tray during application by separate collection of contaminated instruments (without laying back into the insert/tray). Pre-clean the contaminated instruments, then sort them back into the insert/tray and clean, disinfect and sterilize the completely equipped insert/tray.

Additionally, please note the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA).



Attention:

In case of some instruments additional or deviating procedures are required (▶ see chapter 10 "Specific aspects").

Processing of Instruments

2. Cleaning and disinfection

2.1 Basic Information

If possible, we recommend to use an automated procedure (WD) for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered¹.

The pre-treatment step has to be performed in both cases.

¹ In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under responsibility of the user is required.

Processing of Instruments

2.2 Pre-treatment

Please remove coarse impurities from the instruments directly after application (within a maximum of 2 h).

Procedure:

1. Remove the instruments from the insert/tray and disassemble the instruments and the insert/tray as possible (▶ see chapter 10 „specific aspects“).
2. Rinse the instruments and the insert/tray at least 1 min under running water (temperature < 35 °C/95 °F).
Agitate movable parts at least three times during pre-rinsing.
If applicable (▶ see chapter 10 „specific aspects“):
Rinse all lumens of the instruments three times with a syringe (minimum volume 2 ml). Agitate movable parts at least three times during pre-cleaning.
3. Soak the disassembled instruments and the insert/tray for the given soaking time in the pre-cleaning solution² (ultrasonic bath, ultrasound not activated) so that the instruments and the insert/tray are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at beginning of soaking, aids ▶ see chapter 10 „specific aspects“). Agitate movable parts at least three times during pre-cleaning.
If applicable (▶ see chapter 10 „specific aspects“):
Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 2 ml) and of a suitable rinsing adapter.
4. Activate ultrasound for an additional soaking time (but not less than 5 min).
5. Then, remove the instruments and the insert/tray of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Agitate movable parts at least three times during post-rinsing.
If applicable (▶ see chapter 10 „specific aspects“):
Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 2 ml).

² In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (▶ see chapter 8 „material resistance“). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.

Processing of Instruments

Please note following points during selection of the cleaning detergent²:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (▶ see chapter 8 „material resistance“)

Please note the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

² In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (▶ see chapter 8 „material resistance“). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.

Processing of Instruments

2.3 Automated cleaning/disinfection (WD [Washer-Disinfector])

Please note following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A_0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Processing of Instruments

Please note following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (▶ *see chapter 8 „material resistance,)*

Please note the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

Procedure:

1. Disassemble the instruments and the tray as possible and remove the big holders of the insert/tray (▶ *see chapter 10 „Specific aspects“, Figure 1 to 4).*
2. Transfer the disassembled tray, the insert equipped with the remaining instruments (▶ *as instructed in chapter 10 “Specific aspects“, Figure 1 to 4)* and the disassembled instruments/holders (by use of a small pieces basket) in the WD (pay attention that the instruments have no contact).
3. Start the program.
4. Remove the instruments, insert and tray of the WD after end of the program.
5. Check and pack the instruments immediately after the removal (▶ *see chapters 3 „check,,, 4 „maintenance,,, and 5 “packaging,,, if necessary after additional post-drying at a clean place).*

The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher Mediclean (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Processing of Instruments

3. Check

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged instruments (for limitation of the numbers of reuse cycles ▶ *see chapter 9 „reusability“*). Still dirty instruments are to be cleaned and disinfected again.

Processing of Instruments

4. Maintenance

Reassemble instruments again (▶ *see chapter 10 "specific aspects"*).

Instrument oils must not be used.

Reassemble trays again (▶ *see chapter 10 "specific aspects"*).

Return the big holders back into the insert/tray (▶ *see chapter 10 "specific aspects"*).

Processing of Instruments

5. Packaging

Please insert the cleaned and disinfected instruments in the corresponding inserts/trays and **pack them in single-use sterilization packagings (single packaging), which fulfill the following requirements (material/process):**

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage

For the maximum weight of packaging ▶ *see chapter 10 "specific aspects"*.

Processing of Instruments

6. Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure^{3,4} (with sufficient product drying⁵)
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

³ at least three vacuum steps

⁴ The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, requires significantly longer sterilization times as well as a sterilizer, procedure, parameter, and product specific validation under sole responsibility of the user.

	fractionated vacuum/dynamic air removal	gravity displacement
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min ⁵	not recommended
Germany	at least 5 min ⁶ at 134 °C (273 °F)	not recommended
other countries	at least 4 min ⁶ at 132 °C (270 °F) / 134 °C (273 °F)	not recommended

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic and doctor's practice as well as the specified procedure were considered.

⁵ The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

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

⁶ respectively 18 min (inactivation of prions, not relevant for USA)

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

Processing of Instruments

7. Storage

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

Processing of Instruments

8. Material resistance

Please ensure that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- stronger lyes (maximum admitted pH-value 10.3, neutral/enzymatic or weak alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments and inserts (including tray) by use of metal brushes or steel wool.

Please do not expose any instruments and inserts (including tray) to temperatures higher than 138 °C (280 °F)!

9. Reusability

The instruments can be reused – in case of adequate care and if they are undamaged and clean – as indicated in ► *chapter 10 “specific aspects”*. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

Processing of Instruments

⁷ REF : Art. no/Reference number

10. Specific aspects

10.1 Trays

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
SKYOT100	SKY OP-Tray 100 with instruments	-	standard
580DRIVE	Full Range Driver Kit screwdriver set for contra-angles with instruments	-	standard

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF			
4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
<p>pre-cleaning only required if used instruments returned back to the insert/tray or insert/tray visually contaminated: removal of all instruments/ removal of the big holders (for SKYTWPRO, copaSKY L 5.2 [DT, 3.5/4.0, 4.5/5.0, 6.0]), removal of the depth stop box and removal of the insert out of the tray disassemble tray brushing inside and outside</p>	n.a.	<p>without the big holders and the concerning instruments (SKYTWPRO, copaSKY L 5.2 [DT, 3.5/4.0, 4.5/5.0, 6.0])/ insert equipped with all further instruments/outside the disassembled tray) big holders as well as SKYTWPRO, copaSKY L 5.2 (DT, 3.5/4.0, 4.5/5.0, 6.0) and depth stops in small pieces basket depth stop box separated without any depth stops</p>	<p>lubrication not admitted</p> <p>assembled return the big holders back into the insert return the insert into the tray</p>
<p>pre-cleaning only required if used instruments returned back to the insert/tray or insert/tray visually contaminated: removal of all instruments/ removal of the big holders in the bottom of the tray (for SKYTWPRO, laboratory handle and adapters)/removal of the small box/removal of the insert out of the tray/disassemble tray brushing inside and outside</p>	n. a.	<p>without the big holders in the bottom of the tray and the concerning instruments (SKYTWPRO, laboratory handle and adapters)/ insert equipped with all further instruments/insert outside the tray big holders as well as SKYTWPRO, laboratory handle and adapters in small pieces basket small box separated without any instruments and with opening downwards</p>	<p>lubrication not admitted</p> <p>return the big holders back into the tray return the insert into the tray</p>

8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
fully equipped, inside single-use sterilization packaging	fully equipped, inside single-use sterilization packaging	1000	250
fully equipped, inside single-use sterilization packaging	fully equipped, inside single-use sterilization packaging	400	250

Processing of Instruments

⁷ REF : Art. no/Reference number

10.2 Torque wrench and accessories

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
SKYTWPRO	SKY Torque Wrench Pro	-	standard dental floss/ superfloss
SKYTWCON	SKY Connector Pro	2 ml (single-use syringe)	standard conical interdental brush (3-6 mm)
SKY-SD80	SKY laboratory handle incl. SKY-SD22	-	standard conical interdental brush (3-6 mm)
SKYSM453 SKYSM555	SKY seating adapter 4.53 SKY seating adapter 5.55	2 ml (single-use syringe)	standard conical interdental brush (3-6 mm)
SKY-PI22 SKY-DV12	SKY parallel indicator 2.0 + 3.0 mm SKY drill extension	2 ml (single-use syringe)	standard conical interdental brush (3-6 mm)

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF			
4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
<i>dismantle (by pressing the button)</i> head: brush inside and outside body: brush outside, clean gaps by use of untreated and unwaxed interdental floss	n. a.	dismantled, outside the tray (small pieces basket)	lubrication not admitted
brushing inside and outside flushing, agitate spring washer	n. a.	in the insert (integrated holder)	lubrication not admitted
<i>dismantle (by unscrewing and removing the clamping nut)</i> clamping nut: brush inside (especially internal threat) and outside, flushing body: brush outside (especially external threat)	n. a.	dismantled, outside the tray (small pieces basket)	lubrication not admitted
brushing inside and outside flushing	n. a.	outside the tray (small pieces basket)	lubrication not admitted
brushing inside and outside flushing	n. a.	in the insert (integrated holder)	lubrication not admitted

8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
mounted, inside the tray (separate holder)	mounted, inside the tray (separate holder)	-	250
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250
mounted, inside the tray (separate holder in bottom of Full Range Driver Kit)	mounted, inside the tray (separate holder in bottom of Full Range Driver Kit)	-	250
inside the tray (separate holder)	inside the tray (separate holder)	-	250
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250

Processing of Instruments

⁷ REF : Art. no/Reference number

10.3 Depth stops

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
COPS0540 COPS0550 COPS0560 COPAXS05	copaSKY depth stop ø 4.0 mm L 5.2mm copaSKY depth stop ø 5.0 mm L 5.2mm copaSKY depth stop ø 6.0 mm L 5.2mm copaSKY depth stop Twistdrill L 5.2mm	2 ml (single-use syringe)	standard conical interdental brush (3-6 mm)
SKYXST06 SKYXST08 SKYXST10 SKYXST12 SKYXST14 SKYXST16 SKYS0840 SKYS0845 SKYS1040 SKYS1045 SKYS1240 SKYS1245 SKYS1440 SKYS1445 SKYS1640	SKY depth stop Twistdrill L 06 mm SKY depth stop Twistdrill L 08 mm SKY depth stop Twistdrill L 10 mm SKY depth stop Twistdrill L 12 mm SKY depth stop Twistdrill L 14 mm SKY depth stop Twistdrill L 16 mm SKY depth stop ø 4.0 mm L 08 mm SKY depth stop ø 4,5 mm L 08 mm SKY depth stop ø 3,5/4,0 mm L 10 mm SKY depth stop ø 4,5 mm L 10 mm SKY depth stop ø 3,5/4,0 mm L 12 mm SKY depth stop ø 4,5 mm L 12 mm SKY depth stop ø 3,5/4,0 mm L 14 mm SKY depth stop ø 4,5 mm L 14 mm SKY depth stop ø 3,5/4,0 mm L 16 mm	2 ml (single-use syringe)	standard conical interdental brush (3-6 mm)

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF

4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
brushing inside and outside flushing	n. a.	outside the tray (small pieces basket)	lubrication not admitted
brushing inside and outside flushing	n. a.	outside the tray (small pieces basket)	lubrication not admitted

8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
inside the tray (separate holder)	inside the tray (separate holder)	-	250
inside the tray (depth stop box)	inside the tray (depth stop box)	-	250

Processing of Instruments

⁷ REF : Art. no/Reference number

10.4 Moulder

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
SKYC-SM6 SKYC-WM6 mSKYXWM6 mSKYXWM7	whiteSKY moulder for ratchet whiteSKY moulder for contra-angle mini SKY moulder for contra-angle mini SKY moulder for contra-angle long	2 ml (single-use syringe with needle)	standard conical interdental brush (3-6 mm)

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF			
4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
brushing inside and outside back-flushing	n. a.	in the insert (integrated holder)	lubrication not admitted
8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250

Processing of Instruments

⁷ REF : Art. no/Reference number

10.4 Mounter

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
SKY-STK1 SKY-STK5 SKY-STK6 SKY-WTK5 SKY-WTK6 SKY-SD16 SKY-SD22 SKY-SD25 SKY-SD28 COPACK5 COPACK6	SKY TK-mounter for ratchet extra short SKY TK mounter for ratchet short SKY TK mounter for ratchet long SKY TK mounter contra-angle short SKY TK mounter contra-angle long SKY prosthetic key short 16 mm SKY prosthetic key for contra-angle short SKY prosthetic key long 25 mm SKY Prosthetic key for contra-angle long copaSKY TK mounter contra-angle short copaSKY TK mounter contra-angle long	-	standard

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF

4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
standard	n. a.	in the insert (integrated holder)	lubrication not admitted

8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250

Processing of Instruments

⁷REF : Art. no/Reference number

10.5 Screwdriver

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
31000101	Screwdriver 1 long Torx 6	2 ml (single-use syringe)	standard conical interdental brush (3-6 mm)
31000102	Screwdriver 2 long slotted 1.6		
31000103	Screwdriver 3 long slotted 2		
31000105	Screwdriver 5 long Allen 0.05"		
31000106	Screwdriver 6 long Allen 0.9		
31000107	Screwdriver 7 long Allen 1.0		
31000108	Screwdriver 8 long Allen 1.2		
31000109	Screwdriver 9 long Allen 1.8		
31001011	Screwdriver 11 long Square 1.3		
31001012	Screwdriver 12 long Torx 5.5		
31000K01	Screwdriver 1short Torx 6		
31000K02	Screwdriver 2 short slotted 1.6		
31000K03	Screwdriver 3 short slotted 2		
31000K04	Screwdriver 4 short Allen 0.03"		
31000K05	Screwdriver 5 short Allen 0.05"		
31000K06	Screwdriver 6 short Allen 0.9		
31000K07	Screwdriver 7 short Allen 1.0		
31000K08	Screwdriver 8 short Allen 1.2		
31000K09	Screwdriver 9 short Allen 1.8		
31000K11	Screwdriver 11 short Square 1.3		
31000K12	Screwdriver 12 short Torx 5.5		

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF

4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
brushing inside and outside flushing	n. a.	in the insert (integrated holder)	lubrication not admitted
8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250

Processing of Instruments

⁷ REF : Art. no/Reference number

10.5 Screwdriver

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
310W0101	Screwdriver 1 long Torx 6 contra-angles	-	standard
310W0102	Screwdriver 2 long slotted 1.6 contra-angles		
310W0103	Screwdriver 3 long slotted 2 contra-angles		
310W0105	Screwdriver 5 long Allen 0.05" contra-angles		
310W0106	Screwdriver 6 long Allen 0.9 contra-angles		
310W0107	Screwdriver 7 long Allen 1.0 contra-angles		
310W0108	Screwdriver 8 long Allen 1.2 contra-angles		
310W0109	Screwdriver 9 long Allen 1.8 contra-angles		
310W01011	Screwdriver 11 long Square 1.3 contra-angles		
310W01012	Screwdriver 12 long Torx 5.5 contra-angles		
310W0K04	Screwdriver 4 short Allen 0.03" contra-angles		

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF			
4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
standard	n. a.	in the insert (integrated holder)	lubrication not admitted
8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250

Processing of Instruments

⁷ REF : Art. no/Reference number

10.6 SKY drills

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
SKY-DR41 SKY-DP06 SKY-DP08 SKYDT13L SKYDT23K SKYDT23L SKYCD35n SKYXCD35 SKYXCD40 SKYXCD45 SKYXCD55 SKYD1235 SKYD1240 SKYD1245 SKYD1255 SKYD3435 SKYD3440 SKYD3445 SKYD3455 COPACD60 COPD1260 COPD3460	SKY bone bur ø 4.1 mm SKY pilot drill short shaft SKY pilot drill long shaft SKY Twistdrill ø 1.3 mm L 6-14 mm SKY Twistdrill short ø 2.25 mm L 6-16 mm SKY Twistdrill long ø 2.25 mm L 6-16 mm narrowSKY Crestal drill 3.5 N SKY crestal drill ø 3,5 mm SKY crestal drill ø 4,0 mm SKY crestal drill ø 4,5 mm SKY crestal drill ø 5,5 mm SKY Drill for hard bone ø 3.5 mm L 10-16 mm SKY Drill for hard bone ø 4.0 mm L 08-16 mm SKY Drill for hard bone ø 4.5 mm L 08-14 mm SKY Drill for hard bone ø 5.5 mm L 08-12 mm SKY Drill for medium and soft bone ø 3.5mm L 10-16 mm SKY Drill for medium and soft bone ø 4,0 mm L 08-16 mm SKY Drill for medium and soft bone ø 4,5 mm L 08-14 mm SKY Drill for medium and soft bone ø 5,5 mm L 08-12 mm copaSKY crestal drill ø 6.0 mm copaSKY Drill for hard bone ø 6.0 mm L 05-10 mm copaSKY Drill for soft bone ø 6.0 mm L 05-10 mm	-	standard

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF

4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
standard check for remaining bone material/tissue (and repetition of pre-cleaning if required, discard if still remaining bone material/tissue)	n. a.	in the insert (integrated holder)	lubrication not admitted
8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250, but not more than 12 applications

Processing of Instruments

⁷REF : Art. no/Reference number

10.7 SKYplanX drills

⁷ REF	1 article specification	2 rinsing volume	3 brush/other aids
DP20D235 DP24D235 DP28D235 DCR35L20 DCR40L20 DCR45L20 DCR35L28 DCR40L28 DCR45L28 D120D330 D120D380 D124D330 D124D380 D128D330 D128D380 D120D430 D124D430 D128D430 D320D306 D320D356 D320D406 D324D306 D324D356 D324D406 D328D306 D328D356 D328D406	SKYplanX Pilot drill ø 2.35 mm L 20 mm SKYplanX Pilot drill ø 2.35 mm L 24 mm SKYplanX Pilot drill ø 2.35 mm L 28 mm SKYplanX crestal drill ø 3.5 mm L 20 mm SKYplanX crestal drill ø 4.0 mm L 20 mm SKYplanX crestal drill ø 4.5 mm L 20 mm SKYplanX crestal drill ø 3.5 mm L 28 mm SKYplanX crestal drill ø 4.0 mm L 28 mm SKYplanX crestal drill ø 4.5 mm L 28 mm SKYplanX Final drill ø 3.30 mm D1 L 20 mm SKYplanX Final drill ø 3.80 mm D1 L 20 mm SKYplanX Final drill ø 3.30 mm D1 L 24 mm SKYplanX Final drill ø 3.80 mm D1 L 24 mm SKYplanX Final drill ø 3.30 mm D1 L 28 mm SKYplanX Final drill ø 3.80 mm D1 L 28 mm SKYplanX Final drill ø 4.30 mm D1 L 20 mm SKYplanX Final drill ø 4.30 mm D1 L 24 mm SKYplanX Final drill ø 4.30 mm D1 L 28 mm SKYplanX Final drill ø 3.06 mm D2/D3/D4 L 20 mm SKYplanX Final drill ø 3.56 mm D2/D3/D4 L 20 mm SKYplanX Final drill ø 4.06 mm D2/D3/D4 L 20 mm SKYplanX Final drill ø 3.06 mm D2/D3/D4 L 24 mm SKYplanX Final drill ø 3.56 mm D2/D3/D4 L 24 mm SKYplanX Final drill ø 4.06 mm D2/D3/D4 L 24 mm SKYplanX Final drill ø 3.06 mm D2/D3/D4 L 28 mm SKYplanX Final drill ø 3.56 mm D2/D3/D4 L 28 mm SKYplanX Final drill ø 4.06 mm D2/D3/D4 L 28 mm	-	standard

SPECIFIC/ADDITIONAL PROCEDURE IN CASE OF

4 pretreatment	5 manual cleaning/ disinfection	6 automated cleaning/ disinfection	7 Maintenance
standard check for remaining bone material/tissue (and repetition of pre-cleaning if required, discard if still remaining bone material/tissue)	n. a.	in the insert (integrated holder)	lubrication not admitted
8 packaging	9 sterilization	10 Maximum weight of packaging [g]	11 maximum admitted cycle number
in the insert inside the tray (integrated holder)	in the insert inside the tray (integrated holder)	-	250, but not more than 12 applications

Processing of Instruments

10.8 Figures

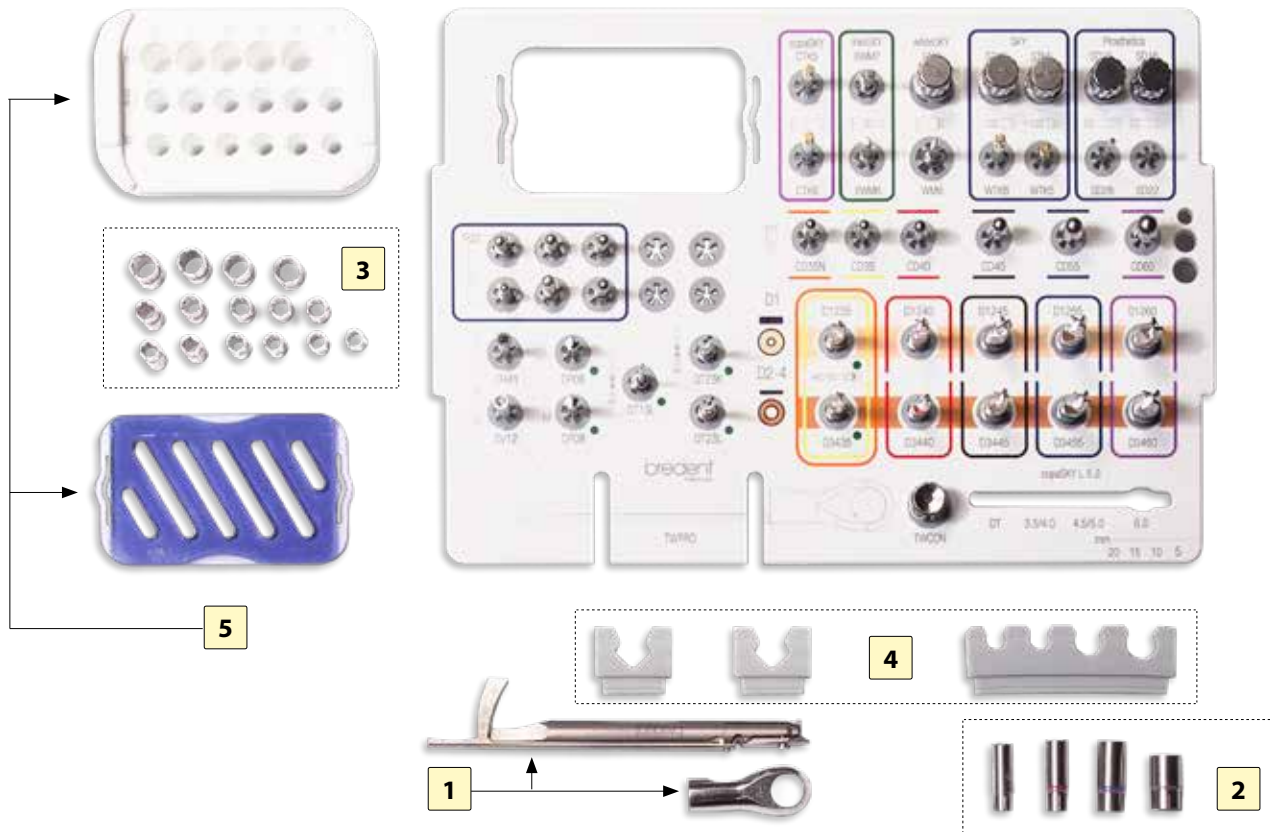


Figure 1

Partly equipped insert (SKYOT100) with removed big holders, depth stop box and instruments for the automated cleaning/disinfection in the WD.

1 *Disassembled SKY Torque Wrench Pro*

2 *copaSKY depth stops*

3 *SKY depth stops*

4 *Silicone holders*

5 *Disassembled depth stop box*

Processing of Instruments

10.8 Figures

**Figure 2**

Dismantle SKYTWPRO by pressing the button/clamping **1** and remove the head from the handle (in direction of arrow). For reassembly push the head back on the handle.

Processing of Instruments

10.8 Figures**Figure 3**

Disassembled tray (SKYOT100) for the automated cleaning/disinfection in the WD.

Processing of Instruments

10.8 Figures



Figure 4

Disassembled tray (580DRIVE) with removed big holders and equipped insert with removed and disassembled small box for the automated cleaning/disinfection in the WD.

