DENDIA

DENTAL INSTRUMENTS

...the first step to a perfect smile

DENTAL INSTRUMENTS

- Full Assortment supplier of Rotary Instruments
- Founded 1947 in Vienna – Austria
- Now located in Feldkirch - western Austria
- Certified by ISO 13485 and MDD RL93/42/EWG
- Highest Quality Standards
- Worldwide customer base

DENTAL INSTRUMENTS

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108010.5950.0010

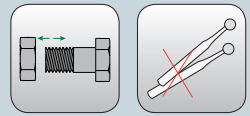
OVERVIEW OF CLEANING PROCEDURE

1. Pre-treatment

- Abrasive impurities need to be removed from the products directly after use (within two hours maximum). To do so, use running water or a disinfectant solution (must not contain aldehydes, its effectiveness should be established, suitable and compatible for the products)

2a. Cleaning and disinfecting

- Place the disassembled products in the cleaning bath for the prescribed contact time and concentration, take care that the products do not touch each other
- Products with lumen: rinse all instrument lumens 5 times at the beginning and or at the end of the contact time using a disposal syringe and a cannula
- Take the products out of the cleaning bath and rinse at least 3 times thoroughly with water
- Check the products
- Dry the products by blowing them dry using filtered pressurised air (Use only filtered air for drying and water that is either sterile or low in germs and endotoxins)
- Wrap the products

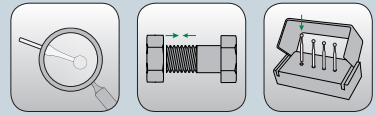


2b. Cleaning and disinfecting with disinfector / RDG (MACHINE CLEANING)

- The effectiveness of the disinfector has to be certified
- Place the disassembled products in the disinfector and take care that the products do not touch each other
- Start the program
- Remove the products from the disinfector after the program has finished
- Check and wrap the products straight after removal if possible
- Ensure that the disinfector is regularly maintained and checked. Use only filtered air for drying and water that is either sterile or low in germs and endotoxins

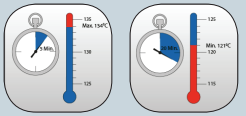
3. Checking / Maintenance / Packaging

- Check the products for corrosion, damaged surfaces, bare patches, broken, chipped-off edges, deformations or impurities and eliminate damaged products. Products that are still contaminated need to be cleaned and disinfected once more
- Arrange the cleaned and disinfected products in the dedicated bur block / sterilisation tray.
- Wrap the products, bur blocks, sterilisation trays using disposable sterilisation packaging (disposable or double packaging) or sterilisation containers



4. Sterilisation

› Steam sterilisation: use of a fractional vacuum process or a gravitation process
› Maximum sterilisation temperature 134°C (273°F)
› At least 3 min (or 18 min at prion deactivation) at 132°C (270°F) / 134°C (273°F) and drying time of 20 min



5. Storage

› The products need to be stored in sterilisation wrapping in a dry and dust-free place. Please note the storage-life resulting from the validation of the sterilisation wrapping

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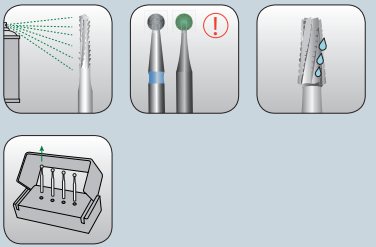
› New unsteril supplied instruments must be prepared befor first use.
› Instruments made of tool steel are not suitable for sterilisation without an appropiate pretreatment.
› When cleaning instruments unprotected against corrosion (like steel instruments) a corrosion-inhibiting disinfectants and cleaning agents must be used and they have to be pretreated with rust preventing spray before sterilisation.
› Furthermore, make sure that instruments of different materials should never be reprocessed together.
› Use particular care during the cleaning of the grinding surfaces of the instruments and ensure that all residues are removed by using a brush.
› In case of severe contamination of the instrument, it is recommended to use a ultrasonic bath for cleaning.
› Usage of protection gloves during work with contaminated instruments is highly recommended!
› Bur blocks / instrument trays:
  » Cleaning and disinfecting only without products being loaded (products must not be cleaned and disinfected whilst they are in the bur block / instrument tray)
  » Burblocks and other instruments made of aluminum (or other light metal) are not suitable for cleaning using a disinfector RDG
› Please follow the manufacturer's instructions and the maintenance specifications for using of the autoclave and the disinfector.
› The method of use, reaction time and suitability of disinfectants and cleaning agents for certain types of instrument are covered by the manufacturers 'instructions.



This is a comprehensive discription of our detailed reprocessing advices. This can be found on our website, in our catalogue on page 16

Newly delivered unsterile instruments must be prepared accordingly before first use!

ORDER INFORMATION & GENERAL INFORMATION

CATALOG VIEW

Figure	660
Shank	FG
Ø	025
Type	ARK
L mm	7.0
📦	5
alt. Shank	RA

L mm Length of workingpart

Packaging unit

ORDER NUMBER

660.FG.025.ARK

660.RA.025.ARK

optional shank if available

SHANK TYPES

DESCRIPTION	∅	←→*	ISO	
Right angle	2,35 mm	22 mm	204	RA
Right angle, long	2,35 mm	26 mm	205	RAL
Friction Grip	1,60 mm	19 mm	314	FG
Friction Grip, long	1,60 mm	21 mm	315	FGL
Friction Grip, extra long	1,60 mm	25 mm	316	FGXL

* The total lenght of instruments can be shorter or longer according to type of construction.

RECOMMENDED SPEED

DIAMETER Ø	DIAMONDS & CARBIDES		ABRASIVES	
	Friction Grip FG	Right Angle RA	Friction Grip FG	Right Angle RA
	min^{-1}			
005	300.000	160.000	80.000 – 100.000	15.000 – 25.000
006				
007				
008				
009				
010				
012				
014				
016	280.000			
018	250.000			
021	210.000			
023	190.000			
025	180.000	120.000		
027	160.000			
028	150.000			
029				
030				

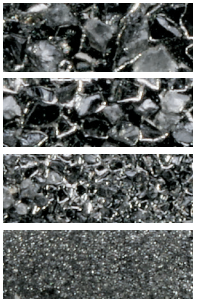
These are general guide speeds, specific recommended speeds for surgery instruments can be found on the product-related page.
To over exceed the given rotation speed can lead to impairment of the eficiency of the products and/or be of danger for the patient as well as the user. The choice of the working speed for a specifc application case is determined by the material subsequently to be used, the instrument power, and the maximal down force pressure ultimately decided upon by the user.

- → To produce optimum results, turn the rotary instruments at their recommended speeds.
- → Long, pointed instruments tend to oscillate if their maximum permissible speeds are exceeded - this may destroy the instruments.
- → If the diameter of the working part exceeds that of the shank, powerful centrifugal forces may build up at high speeds which may bend the shank and/or fracture the instruments. The maximum permissible speed must therefore never be exceeded.
- → The recommended speeds are shown in the adjacent diagram. The maximum permissible working speeds are indicated in the manufacturer's information on the packaging.

> ***Non-adherence to the maximum permissible speeds increases the risk of accidents.***

Recommended speeds ↻

DICA - DIAMONDS



	COLOUR CODE	GRAIN		ISO	SIZE OF GRAINS	RECOMENDED APPLICATION
●	green ring	coarse	= G	534	107-181 µm	Pre-grinding
●	blue ring	medium		524	64-126 µm	Universal grinding
●	red ring	fine	= F	514	27-76 µm	Burnishing
●	yellow ring	extra fine	= EF	504	10-36 µm	Prefinishing of composites

Dica Diamonds basically consist of the shank plus a hardened, stainless profiled body which is coated with only selected, diamond grains using stateof-the-art electroplating techniques. This guarantees an extremely homogeneous, secure and long-lasting diamond coating. A choice of up to seven different grain sizes is also available for an even better result.

The use of coarse-grained diamonds (ISO 534, 544 and 554) can lead to increased heat generation. When using these products, special care should therefore be taken to ensure sufficient cooling and minimal application force. After using these diamond instruments, finishing should be performed in order to obtain an optimal surface roughness.

Figure	801	801	801	801G	801	801G	801	801G	801	801G	801	801F	801G
Shank	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG
Ø	008	010	012	012	014	014	016	016	018	018	023	023	023
L mm	--	--	--	--	--	--	--	--	--	--	--	--	--
📦	5	5	5	5	5	5	5	5	5	5	5	5	5

Figure	801L	801LG	801L	801LG	801L	801LG	801L	801LG	805	808	808	811G	820F	830
Shank	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG
Ø	010	010	012	012	014	014	016	016	016	010	012	033	016	018
L mm	--	--	--	--	--	--	--	--	1.5	2.7	2.7	4.0	5.0	4.5
📦	5	5	5	5	5	5	5	5	5	5	5	2	5	5

DICA - DIAMONDS

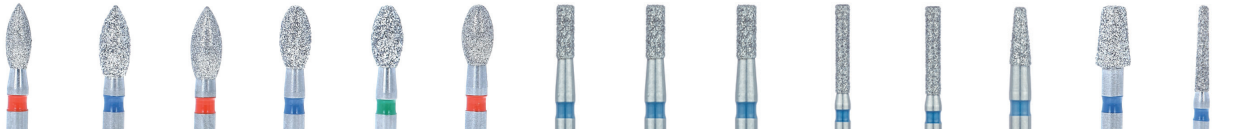


Figure	830F	830	830F	833	833G	833F	835	835	835	837L	837L	845R	845R	850
Shank	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG
Ø	018	023	023	023	023	023	010	012	014	012	014	018	025	014
L mm	4.5	5.0	5.0	4.2	4.2	4.2	3.5	3.5	3.5	8.0	8.0	4.0	4.0	8.0
VPE	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Figure	850G	850F	850	850G	850F	852	852F	852	852G	852F	852	852G	852	852G
Shank	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG
Ø	014	014	016	016	016	012	012	014	014	014	016	016	018	018
L mm	8.0	8.0	8.0	8.0	8.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
VPE	5	5	5	5	5	5	5	5	5	5	5	5	2	5

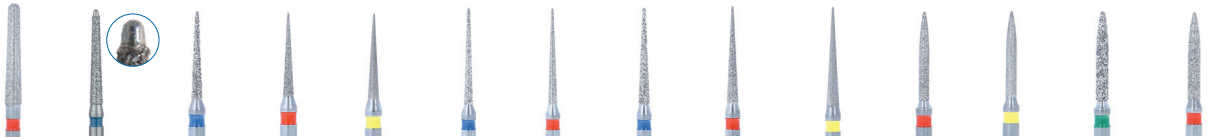


Figure	852F	857	858	858F	858EF	859	859F	859	859F	859EF	862F	862EF	862G	862F
Shank	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG
Ø	018	014	010	010	010	010	010	012	012	012	010	010	012	012
L mm	10.0	10.0	8.0	8.0	8.0	10.0	10.0	10.0	10.0	10.0	8.0	8.0	8.0	8.0
VPE	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Figure	862EF	863G	863F	863EF	881	881G	881F	881	881G	881F	889LF
Shank	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG	FG
Ø	012	012	012	012	012	012	012	014	014	014	009
L mm	8.0	10.0	10.0	10.0	8.0	8.0	8.0	8.0	8.0	8.0	3.5
VPE	5	5	5	5	5	5	5	5	5	5	5

CARBIDES

Figure	C1	C1	C1	C1	C1	C1	C1	C1	C1	C1S	C1S	C1S	C7	C7
Shank	FG	FG	FG	FG	FG	FG	FGXL	FGXL	FGXL	FG	FG	FG	FG	FG
Ø	010	012	014	016	018	023	010	014	018	014	018	023	008	010
L mm	--	--	--	--	--	--	--	--	--	--	--	--	1.8	2.0
VPE	5	5	5	5	5	5	5	5	5	5	5	5	5	5
alt. Shank	RA	RA	RA	RA	RA	RA				RA/RAL	RA/RAL	RA/RAL		

Figure	C21	C21	C23R	C31	C31R	C31R	C33	C33	C33L
Shank	FG	FG	FG	FG	FG	FG	FG	FGXL	FGXL
Ø	012	014	012	010	010	012	012	016	012
L mm	4.1	4.5	4.1	4.1	4.1	4.1	4.1	4.5	6.3
VPE	5	5	5	5	5	5	5	5	5
alt. Shank			RA						

Figure	Finishing Bur	C244K	C379	C379	C48L		Crown Cutter	CX21	CX23	CG35RS	C36R		Amalgam Remover	C31A
Shank		FG	FG	FG	FG			FG	FG	FG	FG			FG
Ø		016	018	023	012			012	012	012	012			012
L mm		8.0	3.5	4.2	8.0			4.0	4.0	3.6	4.0			5.3
VPE		5	5	5	5			5	5	5	5			5
alt. Shank			RA	RA										

	COLOUR CODE	DESCRIPTION	
●	green ring	agressive	high cutting effi-ciency
○	Finishing burs without Ring	fine	8-12 Blades

ABRASIVES






Figure		601		645		660		661		662			661	
Shank		FG		FG		FG		FG		FG			FG	
Ø		030		028		025		025		030			025	
Type		ARK		ARK		ARK		ARK		ARK			GRN	
L mm		--		7.0		7.0		7.0		6.0			7.0	
VPE		5		5		5		5		5			5	
alt. Shank		RA		RA		RA		RA		RA			RA	

ABRASIVES	CERAMIC	ACRYLICS	DENTIN	AMALGAM	KOMPOSIT	RECOMMENDED APPLICATION
GREEN – SILICON CARBIDE	✓	✓	✗	✗	✗	Preparing porcelain and acrylics
ARKANSAS	✗	✗	✓	✓	✓	Finishing/Pre-polishing of all types of filling meaterials as well as natural tooth

✓ *recomended* ✓ *suitable* ✗ *not suitable*

Figure		C151	C151		C152		CX162A
Shank	Zekrya	FGL	FGXL	Endo-Z	FGL	Lindemann	FGXL
Ø		016	016		014		016
L mm		10.7	10.7		9.0		11.0
VPE		2	2		2		2
alt. Shank							

ORAL & MAXILLOFACIAL SURGERY	RECOMMENDED	MAXIMUM
Friction Grip FG	80'000 min^{-1}	100'000 – 200'000 min^{-1}

Quality is not a characteristic it is a claim!

INSTRUCTIONS FOR THE PROCESSING (CLEANING, DISINFECTION, AND STERILIZATION) OF INSTRUMENTS from DENDIA GmbH
Issued: August 2017

The medical devices produced and sold by DENDIA GmbH are re-usable unless their label contains explicit information to the contrary. However, as a rule, it is the sole responsibility of the doctor/expert using the devices to decide whether, depending on the respective case and the potential wear and tear of the products, he can re-use the products and how frequently he uses them. In case of doubt, it is always advisable to discard the products early and to replace them. The manufacturer DENDIA GmbH cannot guarantee the faultless function and performance of the products combined with a maximum degree of safety if the products are overused. These reprocessing instructions apply in principle to all medical devices making up the product range supplied by DENDIA GmbH. Any particular features and/or exclusions that only concern individual items or groups of items are referred to separately.

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 dis¬infection 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 bur block during application; otherwise it is necessary to clean and disinfect the bur block as well as all instruments inside (after removal).

Additionally, please pay attention to 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).

SOME INSTRUMENTS REQUIRE ADDITIONAL ASPECTS. FOR THIS, PAY ATTENTION TO CHAPTER "SPECIFIC ASPECTS"

CLEANING AND DISINFECTING

BASIC:
If possible, an automated procedure (WD (Washer-Disinfector)) should be used 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 considered.
The pre-treatment step is to be performed in both cases.

PRE-TREATMENT:
Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h).

Procedure:
1. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F).
2. Soak the instruments at least for the given soaking time in the pre-cleaning solution1 (by the use of an ultrasonic bath) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at least three times after at beginning of soaking, aids see chapter "Specific aspects").
3. Activate ultrasonic treatment for an additional soaking time (but not less than 5 min).
4. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water.
5. In case of still visible contamination repeat steps 2, 3, and 4, otherwise discard the instrument. This is especially relevant for diamond instruments.

Pay attention to following points during selection of the cleaning detergent[1]:
- 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 „material resistance„)

Pay attention to 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 demineralized 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.

[1] 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 „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.

AUTOMATED CLEANING/DISINFECTION (WD (WASHER-DISINFECTOR)):
Pay attention to 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 (A0 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 demineralized 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

Pay attention to 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 „material resistance„)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

PROCEDURE:
1. Transfer the instruments in the WD by the use of a small pieces basket.
2. Start the program.
3. Remove the instruments of the WD after end of the program.
4. Check and pack the instruments immediately after the

removal (see chapters „check„ , „maintenance„ , and "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 forte (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

MANUAL CLEANING AND DISINFECTION:
Pay attention to following points during selection of the cleaning and disinfection detergents:
- fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material
- in case of application of an ultrasonic bath: suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible with the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance„)

Combined cleaning/disinfection detergents should not be used. Only in case of extremely low contamination (no visible impurities) combined cleaning/disinfection could be used.

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only demineralized 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.

PROCEDURE:
CLEANING
1. Soak the instruments for the given soaking time in the cleaning solution (by the use of a ultrasonic bath) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at least three times after at beginning of soaking, aids see chapter "Specific aspects").
2. Activate ultrasonic treatment for an additional soaking time (but not less than 15 min).
3. Then, remove the instruments of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water.
4. Check the instruments (see chapters „check„ and „maintenance„).

DISINFECTION
5. Soak the instruments for the given soaking time in the dis¬infectant solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments.
6. Then, remove the instruments of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water.
7. Dry and pack the instruments immediately after the removal (see chapter „packaging„, if necessary after additional post-drying at a clean place).

The fundamental suitability of the instruments for an effective cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the pre-cleaning and cleaning detergent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt) considering the specified procedure.

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 re-use cycles see chapter „reusability„). Still dirty instruments are to be cleaned and disinfected again.

MAINTENANCE
Instrument oils or grease must not be use with the exception of steel instruments. In that case use only instrument oils (white oil) admitted to steam sterilization considering the maximum possible sterilization temperature, with approved biocompatibility and without mono-, di, or triethanolamine as corrosion inhibitor.

PACKAGING
Please insert the cleaned and disinfected instruments in the corresponding bur blocks (if required) and pack them in single-use sterilization packagings (single or double 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 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage

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[2,3] (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 138 °C (280 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

AREA	FRACTIONATED VACUUM/DYNAMIC AIR REMOVAL	GRAVITY DISPLACEMENT
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]	not recommended
other countries	at least 3 min[5] at 132 °C (270 °F) / 134 °C (273 °F), drying time at least 20 min[4]	not recommended

[2] at least three vacuum steps
[3] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, will require significantly longer sterilization times and is to be validated dependent on product, packaging, sterilizer, program, and parameters under sole responsibility of the user.
[4] 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.
[5] respectively 18 min (inactivation of prions, not relevant for USA)

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.

The flash/immediate use sterilization procedure must not be used. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

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

MATERIAL RESISTANCE
Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:
- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 11, neutral/ enzymatic or alkaline cleaner recommended)[6]
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

[6] For the bur blocks alkaline cleaners mast not be applied (maximum admitted pH-value 9).

Please do not clean any instruments and bur blocks by use of metal brushes or steel wool.

Please do not expose any instruments and bur blocks to temperatures higher than 142 °C (288 °F)!

Please do not apply acidic neutralizing agents or cleaning aids.

REUSABILITY
The instruments can be reused – in case of adequate care and if they are undamaged and clean as indicated in chapter "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).

ATTACHMENT A: SPECIFIC ASPECTS

Diamond products and ceramic grinding tools:
- Use particular care during the cleaning of the grinding surfaces and ensure that all residues are removed

Bur blocks/instrument trays:
- Cleaning and disinfecting only without products being loaded (products must not be cleaned and disinfected whilst they are in the bur block/ instrument tray)

Instrument group	brush	specific/additional procedure in case of						maximum admitted cycle number (confirmed by validation, but dependent on specific application)	recommended classification according to KRINKO/RKI/BfArM guidance (only German, with respect to intended use)
		pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection	maintenance	packing	sterilization		
stainless steel instruments	standard	standard	standard	standard	lubrication not admitted	standard	standard	10	critical B
regular steel instruments	standard	standard	standard	standard	lubrication recommended	standard	standard	10	critical B
silicone polisher	standard	standard	standard	standard	lubrication not admitted	standard	standard	5	critical B
all other instruments	standard	standard	standard	standard	lubrication not admitted	standard	standard	10	critical B

GENERAL APPLICATION AND SAFETY INSTRUCTIONS
for the medical device from DENDIA GmbH
Issued: August 2017

- DENDIA GmbH products (dental, maxillary surgery, general surgery,) must only be used by dentists, doctors and/or the respective experts who, due to their training and experience, are intensely familiar with the use of these products and who have the corresponding expertise in the respective specialist fields. The use of surgical products requires relevant expertise and experience in dental implantology, maxillary surgery and/or other surgical fields including diagnosis, preoperative planning and surgical techniques.
- It is the sole responsibility of the doctor in charge who, depending on the respective situation (indication), decides on the actual use of the DENDIA GmbH products for each individual case
- All DENDIA GMBH products have been developed for specific applications. Therefore, inappropriate use can result in the premature wear and tear of the products and put patients and users at risk.

APPLICATION
- In order to avoid damaging the instruments, they must be removed from the blister pack by pulling off the backsheet.
- It is essential to only use turbines as well as hand and angle pieces that are technicaly and hygienically faultless, maintained and cleaned.
- The instruments must be rotating when applied on material. They should not be placed on material and then brought to rotation.
- Rotating instruments need to be clamped as far down as

possible with their speed set before applying them on the object. are used with the rotary instruments.
› Using the instruments for canting or leveraging should be avoided as it increases the risk of breakage.
› Depending on the application, it is recommended to use protective goggles while using the instruments. Users of diamond disks should use a disk protection device.
› Inappropriate use of the products leads to badly executed work and increased risk.
› When working with dry materials, it is recommended to use a suction cleaning device.
› In particular,users of hand tools should take care to use them gently and with consideration.
› The user must at all times avoid touching the instruments and parts without protection (protective gloves should be worn).
› Thermal bone damage caused by rotating and oscillating tools (e.g. pilot burr, conical burr, expansion burr) must at all times be avoided (user training, working at low speed and with sufficient cooling).
› During intraoral application attention has to be made to the fact that the products are protected against aspiration or falling on the floor.

USE OF PRESSURE

› Users of the instruments should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the cutting edges to break off. At the same time,it generates excessive heat.
› The use of excessive pressure when using grinding tools can cause the abrasive particles to break off or the instrument to become clogged and lead to heat generation.
› During polishing, excess pressure can lead to heat generation.
› Due to overheating, excess pressure can damage the dental pulp or, due to broken off cutting edges, it can result in undesired rough surfaces. In such cases, even instrument breakage cannot be excluded.

COOLING

› In order to avoid excessive heat generation during preparation, a sterilewater/sodium chloride solution supplied via a permanent external feeding device should be used to ensure sufficient cooling during use of the instruments.
› When using FG instruments that are more than 22 mm long or whose head diameter exceeds 2 mm, additional external cooling is required.
› Insufficient cooling will lead to irreversible damage to the bone and/or the adjacent tissue.

STORAGE, DISINFECTION, CLEANING AND STERILIZATION

› Unless there is explicit information to the contrary, all DENDIA GmbH products are supplied in non-sterile packaging and, depending on the application, they need to be sterilised prior to use. Prior to their first use on the patient and immediately after each use, all products need to be disinfected and sterilised. Inappropriate cleaning and sterilising of the instruments can result in the patient being infected with harmful bacteria.
› You will find detailed instructions for the disinfecting, cleaning and sterilising of products in the Instructions for the processing of instruments produced by DENDIA GmbH on the previous page. We would also be happy to provide you with these instructions at your request. They are also available on the internet at www.dendiadental.com.
› The products should be stored in appropriate, hygienically maintained containers. The same applies to sterilised instruments. The stored products must be protected from dust, humidity and recontamination. Instructions as to maximum storage duration must be adhered to.

SPEED RECOMMENDATIONS FOR ROTARY INSTRUMENTS

› Following the instrument-specific speed recommendations produces the best results.
› Exceeding the maximum admissible speed (rpm) when using long and pointed instruments tends to produce vibrations that can lead to the destruction of the instrument.
› When using working parts with diameters exceeding the thickness of the shaft, excessive speed can release great centrifugal forces that may cause the shaft to bend and/or the instrument to break. Therefore, the maximum admissible rpm must never be exceeded.
› Please consult the manufacturer's information (see catalogue or www.dendiadental.com) for the recommended and the maximum admissible speed ranges. Non-compliance with the maximum admissible
speed puts safety at risk.
› Generally, the following rules apply:
– The larger the working part of an instrument the lower the speed
– Surgical instruments: suitable for geared down micromotor hand and angle pieces 10:1 with stable ball bearings. Speed 600 to 800 rpm with physical and, possibly, sterile external cooling or internal cooling when using the respective hand piece.

DISCARDING WORN INSTRUMENTS AND PARTS

› DENDIA GmbH products can principally be reused several times – unless specifically indicated and labelled otherwise. Rotating instruments are subject to wear. The option of and accountability for multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in each case and the possible wear of the products. If in doubt, the products should always be sorted out early and replaced.
› Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.
› Bare patches on diamond instruments indicate a lack of abrasive particles and can be a sign of blunt instruments. This leads to excessive temperatures during instrument use.
› Instruments that are bent and/or do not run true should be discarded forthwith.
› With the reuse of disposable products the risk of infection cannot be excluded and a risk-free functional safety cannot be guaranteed.

ADDITIONAL INSTRUCTIONS REGARDING THE USE OF TREPANS

› When using trepans, you have to proceed with particular care. For example, it is advisable not to exceed the recommended rpm speed ranges.
› In order to prepare for the actual use of a trepan, it should be set to produce counter-clockwise rotations creating a groove in the bone. Afterwards the trepan can be inserted into this groove and, using clockwise rotations, it can be moved further down.
› 
Carrying out a prior X-Ray is essential to establish the maximum possible drilling depth and to maintain the necessary distance, for example, to the mandibular nerve. As an additional safety measure to spare the nerve, the axial direction of the trepan countersink attachment, based on the sagittal level of the ascending branch, must be milled laterally at an angle of approx. 15-20°.

FURTHER COMMENTS:

› Due to statutory regulations, returned goods can, on principle, only be accepted if the complete batch number is provided. This number can be found on the product pakkaging.

DENDIA

DENTAL INSTRUMENTS

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CE 0483