

## General Instructions for Use and Safety

### For rotating dental and surgical instruments

#### Products

These General Instructions for Use and Safety are applicable for all Frank Dental instruments listed below. They are intended to support their safe use and reprocessing. Detailed information on the instruments used can be found on the labels of the respective packaging and at [www.frank-dental.com](http://www.frank-dental.com).

Information on bulk products such as endodontic products should be requested from the respective manufacturer. Single-use products marked as such are included for the sake of completeness. The cleaning, reprocessing and sterilization instructions are not applicable to any single-use product.

#### Indications

Instruments	Indications	UMDNS code
Carbide burs and finishers	<b>Carbide burs</b> are mainly used for cavity preparation (removal of carious tooth substance and preparing teeth for restorations such as fillings or crowns), for excavation (removal of carious dentin), to remove old fillings, and in dental laboratory procedures. Furthermore, carbide burs (especially spherical ones) are used to access the dental pulp and to remove the roof of the pulp chamber as part of an endodontic treatment. Their hardness also makes carbide burs suitable for removing metal fillings (amalgam fillings) or metal crowns or bridges. <b>Carbide finishers</b> with a fine grit are used for finishing and smoothing resin materials (composites) and all other conventional filling materials, as well as for finishing enamel margins (smoothing of cavity walls and edges).	16-668
Surgical burs and cutters	<b>Surgical burs and cutters</b> are used in oral surgery. Their main areas of application are apicoectomies, the preparation of bone tissue, exposing third molars, exposing tooth roots, cutting teeth (hemisection), or shortening tooth sockets in the alveolar ridge.	16-668
Steel burs and finishers	<b>Steel burs</b> are mainly used for cavity preparation (removal of carious tooth substance) when drilling or milling dentin and for trimming materials that are not too hard. <b>Steel finishers</b> with a fine grit are designed for smoothing surfaces. They are used for finishing enamel margins (i.e., the smoothing of cavity walls and edges)	16-669
Diamond burs	<b>Diamond burs</b> are primarily used when working on dental enamel, i.e., when preparation teeth for crown restorations crown restorations or cavity fillings. They are available almost exclusively with FG shanks and are particularly suitable for use in dental turbines and special (high-speed) contra-angle attachments.	16-670
Abrasive ceramic instruments and elastic polishers	<b>Abrasive ceramic instruments</b> are only exceptionally used to prepare dental hard tissue; they are mainly used to work on metal, such as when adjusting fillings or indirect dental restorations. <b>Elastic polishers</b> feature fine working surfaces, making them suitable for polishing the surface of resins, ceramics, precious alloys, cast metal, titanium, filling materials, but also the surface of natural teeth.	16-412

Generally, burs are used to work on tooth hard tissue and filling materials (metal and composite resins), while surgical burs are additionally used to work on bone. Finishers are

used to smooth surfaces. Polishers are used to polish surfaces. To this end, all instruments are connected to an active medical device.

#### Target group (patients)

Dental burs are used in patients with damaged dental hard tissue. The aim of the treatment is to relieve pain and maintain the patient's chewing function. Rotating dental instruments are used for prevention, diagnosis, treatment, or

rehabilitation of the teeth and dental restorations. Their main effect is mainly mechanical in nature. The intended target group consists of dental patients in dental offices and clinics.



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## Users

Dental rotary instruments are used in dental offices or clinics. The instruments are connected to a dental bur (straight or contra-angle handpiece) and used by dentists or other

experts familiar with the safe handling of these instruments thanks to prior pertinent training and experience.

## Warnings and precautions

Use all instruments correctly and as appropriate for the intended purpose and only by properly trained users, taking into account the following criteria:

### Intended use

Process all instruments not marked as sterilized before first use. Make sure to use only technically and hygienically flawless turbines and straight or contra-angle handpieces that have been regularly maintained and properly reprocessed. Before the actual procedure, seat the instrument as deeply in the chuck of the handpiece as possible and bring it to the recommended speed. Improper use of the instruments—such as tilting, levering, or exerting improper contact pressure—can lead to poor results and must therefore be avoided at all costs. Avoid unprotected

contact with the instruments. Never rest the handpiece on the working end of the rotating instrument while the latter is still inside the handpiece. Place it on the stand provided for this purpose. Store rotating instruments in the bur box after removing them from the handpiece. Placing a rotating instrument on an open surface such as a table may cause damage to the working end. As a general rule, make sure to avoid rotating instruments touching each other or the workbench or other working surface.

### Rust on rotating instruments

Rust is a corrosion (oxidation) product that forms on iron or steel on contact with oxygen in the presence of water. There are also other substances that may accelerate the formation of rust on your rotating instruments.

Store all rotating instruments in a dry and hygienic environment, protected from dust. In order to prevent the formation of rust, the following ingredients should be avoided

during cleaning or disinfection: Organic, mineral, and oxidizing acids (the minimum admissible pH value is 5.5); strong alkaline solutions (the maximum admissible pH value is 10); organic solvents such as alcohols, ethers, ketones, or petroleum ethers; oxidizing agents such as hydrogen peroxide; halogens such as chlorine, iodine, or bromine; aromatic or halogenated hydrocarbons.

### Bur bath

Depending on their composition, bur baths may be unsuitable for some instruments. Some bur baths are specially approved for specific product groups, such as polishers. Using unsuitable bur baths can cause damage to instruments, such as porosity, fraying, or detachment from the bur shank. The above-mentioned chemicals will compromise the materials and reduce their resistance and are therefore unsuitable for

use. We strictly advise against storing noble and base-metal alloys together!

Strictly adhere to the concentrations, temperatures, and exposure times specified by the manufacturer of the cleaning and disinfectant agents as well as any specifications for rinsing.

### Unsuitable drives

Frank Dental rotating instruments are manufactured pursuant to DIN EN ISO 1797. This entails that their shaft thicknesses and tolerances are aligned to popularly used drives.

Possible problems: Rotating instruments do not fit, run out-of-true, or slip

Clean all drives at regular intervals and check them for proper function.

Do not attempt to repair any drives yourself. Such repairs must always be carried out by specialist service providers approved by the manufacturer of the respective drive. The clamping devices (chucks) of the drives are of vital importance to the service life of the rotating instruments.

Rotating instruments that do not fit into the drive may be dirty and require cleaning.

Inadequate cleaned chucks may adversely affect friction, which may decrease significantly over time.

Improper handled rotating instruments may be scratched or even bend when the drive is running. This in turn will increase the risk of breakage due to augmented centrifugal forces.

If one of the above-mentioned problems occurs, have the drive checked immediately. If necessary, return it to the manufacturer or an approved service provider for repair.

The following manual tests can be carried out quickly for verification:

- Pull on the clamped rotating instrument to check the retaining power of the chuck.
- Wiggle the clamped rotating instrument to check the seating inside the chuck. If the rotating instrument is mobile, the chuck may be defective.
- Use an appropriate instrument to check the concentricity of the rotating instrument.

### Recommended speeds

Do not exceed the maximum permissible speed. The maximum permissible speed and the optimum speed (recommended speed) are indicated on the product-specific packaging. Observe these limits under all circumstances.

Exceeding the maximum recommended speed may result in poor performance or even personal injury.

In addition, exceeding the speed recommendations may result in vibrations that can lead to the destruction of the instrument used

### Working angle and contact pressure

Do not under any circumstances exceed the recommended maximum contact pressure (0.3 to 2.0 N m) to avoid detrimental effects.

Such detrimental effects may include:

- Excessive heat generation that can cause damage to the dental pulp
- Inadequate finishing result such as the creation of rough surfaces
- Damage or in the worst case even breakage of the rotating instrument
- The most extensive consequences of excessive contact pressure are seen with FG instruments. It is therefore important to apply the correct contact pressure.

### Irrigation

Due to the contact forces that arise during dental treatment, the prevention of thermal overload must be ensured by uninterrupted irrigation with a sterile water/saline solution. When using instruments of unusual length (> 22 mm) or head

diameter (> 2 mm), always provide additional external irrigation.

For instruments used on all-ceramic zirconia, it is essential to provide sufficient irrigation to avoid the formation of black lines or stripes on the zirconia.

### Useful life

Given the variety of materials used and the widely divergent application environments, it is not feasible to quote a specific number of use cycles (number of times an instrument is used) for any specific instrument. Accordingly, the values given below are for orientation only. Actual figures may vary depending on the material and the duration of each application.

To ensure the most efficient and effective application of our instruments, we recommend the following use cycles:

Diamond instruments: maximum 3 use cycles

Steel instruments: maximum 5 use cycles

Carbide instruments: maximum 10 use cycles

Surgical Instruments & Cutters: maximum 10 use cycles

Unless expressly indicated and marked otherwise, Frank Dental instruments are generally suitable for multiple use. The practicing dentist alone is responsible for deciding on the multiple use of the instruments and the frequency of use on the basis of the respective application and the potential wear of the products. In case of doubt, we recommend discarding and replacing instruments rather earlier than later.

### Wear PPE (eye, mouth, and hand protection)!

### Application: General principles of cleaning, disinfection, and sterilization

Clean, disinfect, and sterilize all instruments before each use. This applies in particular to first-time use after delivery, since all instruments are delivered non-sterile (cleaning and disinfection after removal of the protective transport packaging, sterilization after packaging).

Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization.

Collect used or soiled instruments separately, directly after use, taking care not to return them to the bur stand or instrument tray to avoid additional contamination of the loaded bur box or instrument tray.

After cleaning and disinfection, return the instruments to their positions in the bur box or instrument tray and sterilize the fully loaded box stand or instrument tray.

As part of your responsibility for the sterility of the instruments during use, please make sure to use only properly validated device-specific and product-specific procedures for cleaning/disinfection and sterilization, to maintain and check the equipment and consumables used (ultrasonic bath, sterilizer) regularly, and to adhere to the validated parameters in each and every cycle.

Given their intended purpose, the instruments may penetrate the skin or mucous membrane during surgical, periodontological, or endodontic procedures, such as root canal preparation, and come into contact with blood, internal tissues, or organs (including wounds). It is therefore recommended that the device be classified in the Critical B risk group when used as intended.

### Limitations on reprocessing



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Unless labeled as single-use products, all instruments can be reused several times. Their period of usability is only limited by wear or damage to the instruments. The physician is responsible for identifying and disposing of damaged or worn instruments at an early stage. In case of doubt, instruments

should be disposed of and replaced earlier rather than later. With each reuse, inspect instruments visually for intactness and cleanliness. In case of residual contamination, the cleaning process must be repeated.

## Cleaning and disinfection

### Revisiting the basics

Reprocess all Instruments in an automated process as recommended by the German Robert Koch Institute (RKI) or comparable national institutions. Observe all RKI

recommendations regarding effective infection control measures in the workplace, including the use of powder-free and latex-free gloves for all procedures.

### Storage and pre-treatment

Immediately after application (within a maximum of 2 hours), remove any visible soils from the instruments with a nylon brush. Do not use metal brushes or steel wool. Immediately place used instruments in a bur bath with a non-protein-fixing and non-aldehyde disinfectant and cleaning solution or rinse under running water. The instructions for use, duration of action, and overall suitability of disinfectants for certain

types of instruments can be derived from the information provided by the manufacturers of these agents and must be strictly observed. The disinfectants used in the pre-treatment only serve to protect the user and are never a substitute for the disinfection step in the mechanical cleaning process as described below.

### Automated reprocessing

Rinse the instruments under running water immediately before automated cleaning.

Place the instruments in suitable stands in a washer-disinfector pursuant to ISO 15883 using the following program sequence:

#### Automated washing/disinfection:

**When selecting an automated washer-disinfector (WD), make sure that:**

- the WD always is of proven effectiveness (e.g. VAH/DGHM or FDA approval/clearance or CE marking pursuant to DIN EN ISO 15883)
- an approved program for thermal disinfection (AO > 3000 or—for older devices—at least 5 minutes at 90°C/194°F) is used wherever possible (chemical disinfection poses a risk of disinfectant residues on instruments),
- the selected program is suitable for the instruments and includes sufficient rinsing cycles
- only sterile water or water with a low germ count (max. 10/ml) and low endotoxin content (max. 0.25 endotoxin units/ml), such as purified water/highly purified water, is used for rinsing,
- the air used for drying is filtered (oil-free, low in germs and particles)

If a WD is designed pursuant to DIN EN ISO 15883 and is regularly inspected and maintained during its service life, it will meet the above requirements with regard to water and air quality.

**When selecting cleaning and disinfecting agents, make sure that:**

- it is basically suitable for cleaning products made of metals and resin materials,
- if no thermal disinfection is performed, a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval/clearance or CE marking pursuant to DIN EN ISO 15883) is added and that this disinfectant is compatible with the cleaning agent used,
- the chemicals used are compatible with the instruments, and
- the concentrations specified by the manufacturers of the cleaning agent and, where applicable, the disinfectant are strictly observed.
- and also that the temperatures and exposure times as well as the specifications for post-rinsing are strictly adhered to.

## Procedure

- Place the instruments in the WD. Make sure that the instruments do not touch each other. To prevent the instruments to be disinfected from damaging each other, place them in suitable instrument stands (e.g., a Burblock FG/RA 02/S from Frank Dental GmbH). Place the instrument stand in the washer-disinfector such that the water jet hits the instruments directly. Load the washer-disinfector with a cleaning detergent at the dosage recommended by the manufacturer.
- Start the program for thermal disinfection.
- Once the program has completed, remove the instruments and dry them comprehensively using compressed air. Check the instruments for cleanliness, damaged surfaces, and deformation. Discard damaged instruments directly. If residual contamination is present, repeat the process until all soil has been removed.
- Re-wrap the instruments as soon as possible after removal from the WD.

The reprocessing is performed by the trained staff in the dental office or clinic. Due to the enormous importance of infection control, it is necessary to reprocess used burs immediately for further use. Dentist should therefore

reprocess the various instruments several times a day. Hygiene and instrument reprocessing are elementary aspects of the curriculum for dentists and dental assistants as parts of the compulsory subjects.

**Frank Dental recommends only automated reprocessing and discourages manual cleaning.**

## Packaging

Assemble the cleaned and disinfected instruments in the designated instrument storage units and wrap them in suitable sterilization packaging that meets the following requirements:

- DIN EN 868-2 ff./DIN EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilization (heat-resistant up to at least 138°C/280°F, sufficient steam permeability)
- Sufficient protection of the instruments and sterile wrapping against mechanical damage
- For individually packaged instruments: The packaging must be large enough to ensure that the seal is not under any tension.

## Sterilization

Instruments of classes Semicritical A + B do not necessarily have to be sterilized. For more information, please consult the RKI guidelines or national equivalents.

Select a packaging material suitable for the instruments and the sterilization process. Follow the instructions of the sterilizer manufacturer.

**Steam sterilization pursuant to DIN EN 13060 using the following parameters is recommended:**

### USA

- Fractionated pre-vacuum (3-fold)
- Sterilization temperature: 134°C (273°F)
- Holding temperature: 4 min (full cycle)
- Drying time: 20 min (prion inactivation)

### Other Countries

- Fractionated pre-vacuum (3-fold)
- Sterilization temperature: 134°C (273°F)
- Holding temperature: 5 min (full cycle)
- Drying time: 10 min or 18 min (prion inactivation)

## Handling of sterile products

Instruments in sterile packaging whose packaging is damaged should be returned to Frank Dental. Instruments in sterile packaging whose packaging is accidentally opened should be re-sterilized.

Note the applicable shelf life resulting from the validation of the sterilization packaging.

## Storage

Until first use, the instruments should be stored at room temperature in their original packaging, protected from dust and moisture.

Rotating instruments should be stored in hygienically maintained stands, trays, or other suitable containers.

The same applies to **sterilized instruments and instruments in sterile packaging**. Protect stored instruments from dust,

moisture, and recontamination. Avoid temperature fluctuations and contact with acids and chemicals.

## Waste disposal

Dispose with residual household waste in a tightly closed container (waste key number: 35 101 – Germany)

## Certificates and Product Data Sheets (PDS)

For the protection of personnel and patients, it is important to closely follow the Instructions for Use and Care appropriate to the respective product group. For this reason, Frank

## Maintenance

Rotating instruments do not require maintenance. Do not use machine oil.

Dental's 24-hour service provides the most up-to-date MSDS along with applicable certificates for the individual products for download on its website, [www.frank-dental.com](http://www.frank-dental.com).

## Manufacturer notes

Frank Dental as the manufacturer confirms that the products marked for re-use are indeed suitable for re-use, taking into account the procedures described.











The user is responsible for ensuring successful reprocessing using the proper materials, equipment, etc. and that the result meets the hygiene requirements. Regular validation of the procedures described here is therefore necessary. The user is responsible for documenting any deviations.











In the event of faulty reprocessing, the reprocessor is liable for damage or personal injury caused by the use of incorrectly reprocessed rotating instruments in the role of Operator within the meaning of the Medical Devices Operator Regulation (MPBetreibV). The reprocessor bears full responsibility for the appropriate reprocessing of the

medical device and its reuse. All warranty claims against Frank Dental GmbH, as well as any claims arising from product liability laws and the Medical Devices Act are excluded in this case.








Always observe the legal regulations applicable in your country as well as the infection control policies of the dental office or clinic. This particularly applies to the different specifications regarding effective prion inactivation. The recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI – [www.rki.de](http://www.rki.de)) and the Federal Institute for Drugs and Medical Devices (BfArM – [www.bfarm.de](http://www.bfarm.de)) for the reprocessing of medical devices or their local equivalents must be observed.






## Pictorial information on indications and application

Symbol	Description
	Legal manufacturer
	Date of manufacture
	Do not reuse
	Lot number
	Order number
	Sterilized by irradiation with gamma rays
	Non-sterile
	Follow instructions for use
	(Reference to the manufacturer's website)
	Read the accompanying information

	Speed
	Packaging unit
	Cavity preparation
	Crown preparation
	Removing existing fillings
	Finishing of restorations
	Root scaling
	Prophylaxis
	Root canal preparation
	Pin technique



	Crown sections
	Maxillofacial surgery
	Orthodontic treatment
	Oral implantology
	Acrylic technique
	Dental model fabrication
	Crown and bridge technique

	Cast-metal restorations
	High-precision laboratory procedures
	Contains hazardous substances (Cobalt)
	Steam Sterilization
	Thermal Disinfection

## CE 0297

Since Frank Dental's rotary instruments are used and applied exclusively by trained professionals, it is not necessary to include Instructions for Use with each product.

Product innovations or new instruments are exemptions from this rule. Such Instructions for Use will be supplied with the products at the time of their introduction.

The most recent version of these "General Instructions for Use and Safety" can be downloaded from [www.frank-dental.com](http://www.frank-dental.com).

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