Information on the reprocessing of resterilisable instruments in accordance with DIN EN 17664, as well as information for products marked as disposables.

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Product:
This information applies to all rotating dental and surgical instruments that G&Z manufactures itself. Information on merchandise that is not delivered by us as the manufacturer must be requested from the respective manufacturer.

G&Z products are: Diamond Instruments, Carbide Burs, Finishers and Maxillofacial Surgery Instruments

Notes on processing:
Instruments supplied non-sterile must always be prepared before first use.

Limitation of reprocessing:
Maximum number of cycles allowed is 10.
The end of a product life is determined by wear (e.B. wear on cutting edges or diamond grain) or damage (e.B. too much contact pressure used or tilted).

Place of usage:
Please note the country-specific requirements and carry out the preparation only in designated rooms/areas.

Hygiene at the workplace: see RKI guideline www.rki.de or valid legal and hygiene regulations in your country.

Cleaning, disinfection and drying by machine:
According to validation.

Risk assessment and classification of medical devices before reprocessing:
The type and scope of reprocessing depend on the use of the medical device. Therefore, the operator is responsible for the correct classification of the medical devices and thus for determining the type and scope of the reprocessing (see KRINKO/BfArM recommendation, point 1.2.1 Risk assessment and classification of medical devices before reprocessing). On the basis of this user-dependent classification, the operator may determine which of the treatment processes listed in this treatment instruction must be carried out.

<table>
<tr><td colspan="2">Instructions:</td></tr>
<tr><td>Gebrauchsort:</td><td>No special requirements.</td></tr>
<tr><td>Storage and transport:</td><td>It is recommended to transport contaminated instruments in a closed container.
It is recommended to reprocess the instrument as soon as possible, maximum within 2 hours of use.</td></tr>
<tr><td>Preparation:</td><td>Wear personal protective equipment (gloves, water-repellent protective coat, face mask or goggles).</td></tr>
<tr><td>Cleaning and Disinfection: Mechanical</td><td>

Cleaning and disinfection device according to DIN EN ISO 158831+2 with thermal program (temperature 90 oC to 95 ^{0C}).
Cleaner mildly alkaline (e.B. ECOLAB Sekumatic@ MultiClean (www.ecolab.com))

1) Place all individual parts in a suitable small parts sieve, or place them on the load carrier in such a way that all internal and external surfaces are cleaned and disinfected.
2) Close RDG and start program, program sequence see table below.
3) Remove medical devices at the end of the program
4) Check for cleanliness (possibly with a magnifying lens 8x or larger) and for dryness of the load and, if necessary, drying with medical compressed air. If contamination residues are still visible, it must be cleaned manually. Only then may the mechanical processing process be repeated.
<table>
<tr><td>Prog.-Step</td><td>Water</td><td>Dosage</td><td>Time</td><td>Temperature</td></tr>
<tr><td>Vorspülen</td><td>KW</td><td></td><td>5 min</td><td></td></tr>
<tr><td>Dose Cleaner</td><td></td><td>200ml MultiClean (0,5%)</td><td></td><td></td></tr>
<tr><td>Clean</td><td>VE</td><td></td><td>10 min</td><td>55 ° C</td></tr>
<tr><td>Rinse</td><td>VE</td><td></td><td>2 min</td><td></td></tr>
<tr><td>Disinfect</td><td>VE</td><td></td><td></td><td>A_0-Wert > 3000 [1] (z.B. 5 min, 90 ° C)</td></tr>
<tr><td>Dry</td><td></td><td></td><td>15 min</td><td>up to 120 ° C</td></tr>
</table>
[1] Authorities may adopt other implementing provisions (parameters for disinfection performance) within their area of competence.
</td></tr>
<tr><td>Maintenance, control and testing:</td><td>All products must be inspected for damage (e.B. bent or fractured instruments or cutting edges, surface damage such as chipped diamond assignments) and wear. Damaged products may no longer be used and reprocessed and must be sorted out.</td></tr>
<tr><td>Packaging:</td><td>Packaging according to DIN EN ISO 11607 or DIN 58953</td></tr>
</table>

Sterilization:	-Use a sterilizer according to DIN EN 13060 type B and/or DIN EN 285. -Start a fractional vacuum process at 134'Cf holding time of at least 3 minutes. 1) Place the packaged medical device in the sterilization chamber. 2) Start the program. 3) At the end of the program, remove the medical device and let it cool. 4) Check the integrity and dryness of the packaging.
Storage:	Storage and storage time according to the specifications of the user.

Additional information:	No special requirements.
Contact to the manufacturer:	

The instructions listed above have been validated by the manufacturer of the medical device as an appropriate procedure for reprocessing the medical device for reuse. It remains the responsibility of the user to ensure that the currently carried out treatment process in the facility achieves the desired and necessary result using equipment, material and personnel. This requires validation and routine control of the process. Similarly, any deviation of the user from the instructions provided must be assessed and evaluated in terms of effectiveness and potentially unfavorable consequences.

Maintenance:
All products must be inspected for damage (e.B. bent or fractured instruments or cutting edges, surface damage such as chipped diamond coverings) and wear. Damaged products may no longer be used and reprocessed and must be sorted out.

Testing:
Instruments that have shortcomings, such as

- blunt cutting edges
- bent or fractured drills, dental
- Surface damage (e.B chipped diamond occupancy) must be sorted out immediately.

Packaging:
In the case of sterile products, care must be taken to ensure that the seal is not under tension, that individual removal is sterile and that the expiry date is visible at all times.

Sterilization:

Equipment steam sterilizer

Procedure in detail:

Steam sterilization process in fractional vacuum process at ^{1340C} in a device according to DIN EN 13060:

1. Fractional procedure
2. Sterilisationstemperatur 134 ^{0}C
3. Holding time 5 minutes (full cycle)
4. Drying time 10 minutes

To avoid staining and corrosion, the steam must be free of ingredients. Attention: Observe the maximum load of the sterilizer.

Storage:

The transport and storage of packaged sterile is well protected against dust, moisture and recontamination. The instruments must be protected against chemicals, acids, heat and extreme temperature fluctuations.

For more information:

Bundesgesundheitsblatt — Gesundheitsforsch- Gesundheitsschutz 2006. 49. XXX-XXX DOI 10.1007/s00103-005-1219-y - Springer Verlag 2005
see Deutscher Zahnärzte Verlag "Das Dental Vademekum", 10th edition

Manufacturer's note:

The manufacturer shall confirm that the products marked for re-use are indeed suitable for re-use, taking into account the procedures described.
The processor is responsible for ensuring that the preparation with the used
Materials, equipment, etc. is successful and meets hygiene requirements. Regular checks of the procedures described here are therefore necessary and possible deviations are to be documented and evaluated by the processor for possible consequences.

Note to users and distributors: Any serious incidents that have occurred in connection with the product must be reported to G&Z Instrumente GmbH and the competent authority of the Member State in which the user is established.