OPERATING MANUAL (INSTRUCTION FOR USE)

Introduction

This Instruction for Use applies to reusable dental instruments manufactured by **AR Instrumed**. These instruments are intended for use by **qualified dental professionals** in clinical settings.

All instruments are supplied **non-sterile** and must be thoroughly cleaned, disinfected, and **sterilized** prior to first use and following each reuse.

AR Instrumed recommends the use of validated cleaning, disinfection, and sterilization procedures as outlined in this document, in accordance with **ISO 17664:2017**.

Disclaimer

The instructions for processing products before first use/reuse herein have been **validated** by **AR Instrumed**. Users are solely responsible for any **deviation** from these instructions, and/or the use of alternative methods for processing. AR Instrumed accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the guide set forth below. The user shall observe safe and lawful practices including, but not limited to, those outlined in this document.

Exams

The Instruments must be **checked** for proper functionality before each use. Surface damage such as scratches, cracks, nicks, notches, etc., as well as bent parts, mean that the instrument must **not be used**. The Product must then be disposed of in accordance with the hospital's standard disposal procedures.

Many of the multi-part instruments, such as Scissors, show oil residues from the production. Please make sure that the instruments are cleaned properly.

Warnings

- Reuse without proper sterilization increases the **risk** of cross-contamination.
- Do not use damaged, corroded, or discolored instruments.
- Avoid **abrasive tools** (e.g., steel brushes) that may damage metal or silicone.

- Do not **soak instruments** in lubricants or incompatible chemicals.
- Do not sterilize in autoclaves with **oil residues**.
- Maximum validated steam sterilization temperature: **134°C (273°F)**.

General Precautions

- Always wear protective clothes for your **safety** (gloves, eye protection wear, and mask).
- **Dispose** of all sharp and contaminated products in accordance with accepted local regulations.
- Do not use labels or identification **markers** directly on the product.
- Use only validated equipment and approved detergents (neutral or mildly alkaline, pH 7–10).
- **Avoid** acidic, aldehyde-based, or chlorine-containing agents.
- **Protect** instruments from abrasion using silicone or plastic inserts in cassettes.

PROCESSING INSTRUCTIONS

Initial Treatment at Point of Use

Immediately after use, instruments should be rinsed with **cold tap water** at a temperature of approximately 20 ± 2°C to remove blood, debris, and other contaminants. It is essential not to allow contaminants to dry on the surface of the instruments, as this can make cleaning more difficult and compromise reprocessing effectiveness. If contaminants have dried, the instruments should be soaked in an aldehyde-free pre-cleaning solution with a pH between 7 and 10 to loosen and remove residues before further cleaning steps.

Containment and Transport

After use, instruments should be **transported** safely to the designated reprocessing area in a manner that prevents damage and minimizes the risk of contamination or injury. It is

important to begin the reprocessing procedure as **soon as possible** after use to prevent the drying of organic material and ensure effective cleaning and sterilization.

Preparation Prior to Cleaning

Visible debris should be removed using soft brushes made of materials such as nylon, polypropylene, or acrylic to avoid damaging the instrument surfaces. The use of **metal brushes or abrasive scrubbing tools** is strictly discouraged, as they may cause scratches, corrosion, or degradation of the instrument's functional surfaces.

Automated Cleaning

For automated cleaning, use a washer-disinfector that complies with EN ISO 15883-1 and -2 standards. A validated detergent with a pH between 7 and 10, containing both disinfecting and corrosion-inhibiting properties, should be used. Instruments must be placed in appropriate **cassettes** or supports during the cycle to prevent contact, mechanical damage, or scratching. **Thermal disinfection** is recommended at a temperature of 90–95°C, achieving an A_0 value of at least 3000. If available, final rinsing should be carried out using distilled or ion-exchanged water to prevent water stains and mineral deposits.

Inspection and Maintenance

After cleaning and disinfection, all instruments must be **visually** inspected under appropriate lighting of at least **500 lux**. Carefully examine each instrument for any signs of damage or defects, including cracks, corrosion, dull cutting edges, faded markings, or bent tips. Instruments that remain dirty or moist after the cleaning cycle must be reprocessed again to ensure they are safe for use. If the **washer-disinfector** leaves any residual moisture, instruments should be dried manually using medical-grade compressed air or a lint-free, non-abrasive cloth to prevent water spots and microbial growth.

Note: Hinged instruments should be lubricated with a medical-grade, steam-permeable instrument oil to ensure smooth operation and prevent corrosion.

Packaging

Before sterilization, instruments should be packaged in validated sterilization pouches that comply with **ISO 11607 and EN 868-5** standards. Sharp or pointed instruments should be double-packed, and **silicone tubing** may be used to cover tips in order to prevent punctures

or damage to the packaging. All pouches must be sealed securely in accordance with the manufacturer's instructions to maintain sterility until use.

Sterilization

Sterilization should be performed using a **pre-vacuum steam sterilizer** that complies with EN 13060 (Class B) or EN 285 standards. The recommended sterilization cycle is **134°C for 3 minutes**, which is preferred for prion deactivation. Alternatively, a cycle of **132–135°C for 4 minutes** may be used. After sterilization, all packaging should be carefully inspected for integrity, dryness, and proper chemical indicator response. If any moisture is detected, the instruments must be repackaged and re-sterilized to ensure sterility is maintained.

Storage

- Store in a clean, dry environment at **15–25°C (59–77°F)**.
- Protect from moisture, sunlight, and physical damage.
- Reprocess if packaging is compromised or expired.

Reuse and Lifespan

- Instruments may be reused if free from defects.
- No fixed limit on reprocessing cycles; inspect regularly.
- Replace instruments showing wear, damage, or loss of functionality.

Contradictions

These devices should not be used with patients, when these are damaged.

Moreover, device(s) should not be used for anything other than their intended use.

Legends	
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EC REP	**AR Instrumed Deutschland GmbH (SRN: DE-AR-000014821)** Döbelner Str., 2A 12627 Berlin-Germany Phone: +4930 91201490 Email: info@ar-instrumed.de
Importer SRN	**AR Instrumed Deutschland GmbH (SRN: DE-AR-000014821)**
CE	The device(s) complies with EU MDR 2017/745 as amended by 2020/561

MD	REF	LOT	QTY	EC REP
Medical Device	**Catalogue Number**	**Lot Code**	**No. of pieces Contained**	**EU Authorized Representative**
				
Manufacturer	**Non-Sterile**	**Keep dry**	**Instruction for Use**	**Caution**