INSTRUCTIONS FOR USE

Reusable Surgical and Dental Hand Instruments: General IFU

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1. Scope of this document

This document applies to all **reusable, non-powered stainless-steel hand instruments** made by BusinessMed Instruments for surgery, plastic and aesthetic surgery, dentistry, orthodontics, ENT, hair restoration, diagnostics and liposuction (handles and cannulas). Examples are scissors, forceps, needle holders, clamps, retractors, hooks, elevators, raspatories, osteotomes, chisels, rongeurs, curettes, scalers, probes, pliers, knife handles and cannulas.

It does **not** apply to single-use products, electrosurgical cables, fibre-optic light cables, light sources or other products that carry their own instructions. Where a product comes with a product-specific IFU, that document takes priority over this general IFU.

Supplied condition	**NON-STERILE.** Clean and sterilise before the first use and before every use after that.
Material	Surgical-grade stainless steel. Where a product contains other materials (for example tungsten carbide inserts, titanium, aluminium, plastic or wooden handles, or coloured or black coatings), these are named on the product label or product page.
Intended users	Qualified surgeons, dentists and other licensed healthcare professionals, and trained reprocessing (CSSD / sterile services) staff.
Patient population	No restriction by age or sex. The choice of instrument for a given patient is the clinician's decision.
Contact with the body	Transient contact (normally less than 60 minutes) with tissue, bone, teeth or body fluids. The instruments are not implants and are not intended to remain in the body.
Calibration	Not required. Measuring instruments (calipers, gauges, rulers) should be checked for legibility and accuracy at each inspection.

2. Intended use

The instruments are manual tools used by trained professionals to cut, dissect, grasp, hold, clamp, retract, elevate, scrape, probe, measure, mark, aspirate or bend, as described by the instrument's name and design. Each instrument may only be used for the task it was designed for.

Contraindications

There are no contraindications for the instruments themselves. Contraindications depend on the surgical or dental procedure and are the responsibility of the treating clinician.

Possible side effects and complications

Complications are related to the procedure and to correct handling, not to the instrument as such. Incorrect use, or use of a damaged or inadequately reprocessed instrument, can cause tissue injury, a broken fragment remaining in the patient, or infection.

3. Warnings

WARNING: non-sterile. Instruments leave our factory clean but not sterile. New instruments may carry traces of polishing compound or protective oil from manufacturing. Remove all protective caps and packaging, then clean, inspect and sterilise every new instrument according to BMI-IFU-G02 before its first use.

- **Use for the intended task only.** Do not use tissue scissors on sutures, wire or cartilage, needle holders on instruments or implants, or forceps as levers. Misuse damages tips, blades and joints and can lead to breakage during surgery.
- **Do not use damaged instruments.** Remove from service any instrument with cracks, bent or broken tips, loose joints, a worn ratchet, pitting or corrosion.
- **Chlorides and strong chemicals cause corrosion.** Do not let instruments come into prolonged contact with saline solution, blood left to dry, bleach (hypochlorite), iodine, or strong acids or alkalis.
- **Do not modify, re-grind, re-plate or repair instruments yourself.** Unauthorised repair can change the steel's hardness and corrosion resistance and voids the warranty.
- **Infection control.** Treat every used instrument as contaminated. Wear suitable protective equipment (gloves, eye protection, fluid-resistant apron or gown) when handling and reprocessing.
- **Prion diseases.** For patients with known or suspected Creutzfeldt-Jakob disease (CJD/vCJD), follow your national guidance; instruments may need to be quarantined or destroyed rather than reprocessed.

4. Precautions for handling

- Handle instruments individually and gently. Do not drop them or throw them into trays or basins.
- Protect tips and cutting edges. Microsurgical and fine-tipped instruments should be kept apart from heavy instruments and fitted with steam-permeable tip protectors.
- Keep ratcheted instruments (needle holders, haemostats, clamps) open or on the first ratchet tooth when not in use. Storing or sterilising them fully closed stresses the box lock.
- Place heavy instruments at the bottom of trays and light or delicate instruments on top.
- Keep instruments made of different metals, or with coatings, apart from stainless steel during cleaning to prevent contact corrosion.
- Use only water-soluble, steam-permeable instrument lubricant. Never use general-purpose, mineral or silicone oils.

5. Before each use

1. Check that the sterile barrier packaging is intact, dry and within the shelf life defined by your facility, and that the sterilisation indicator has changed as expected.
2. Inspect the instrument: clean, dry, no cracks, no corrosion, tips aligned and complete, joints moving smoothly, ratchets holding, cutting edges sharp. The detailed checks are given in BMI-IFU-G02, section 8.
3. Do not use an instrument that fails any check. Set it aside for repair or replacement.

6. After each use

Begin reprocessing as soon as possible. Remove gross soil at the point of use and keep the instruments moist until cleaning, then clean, disinfect, inspect, lubricate, pack and sterilise them as described in **BMI-IFU-G02 – Cleaning, Disinfection & Sterilisation Guide**. The healthcare facility is responsible for using validated equipment and processes and for following its national reprocessing standards.

7. Storage and transport

- Store instruments only when completely dry, in a clean, dry and dust-free place at room temperature, away from chemicals, moisture, insects and direct sunlight.
- Store sterile packs so that the packaging cannot be crushed, punctured or become wet.
- Keep delicate instruments in racks, trays or cases that hold them apart.
- Transport used instruments in closed, puncture-resistant containers.

8. Service life, maintenance and repair

Reusable instruments withstand repeated reprocessing. Their service life is ended by wear, damage or loss of function, not by a fixed number of cycles. Inspect them before every use. Blunt cutting instruments, worn tungsten carbide inserts and misaligned jaws can be restored by BusinessMed Instruments; contact us before sending instruments for service. Used instruments must be cleaned and sterilised before they are sent to us.

Warranty: 5 years on reusable stainless-steel instruments (including kits and sets) against defects in material and workmanship when used and reprocessed according to these instructions. See businessmedinstruments.com/warranty-and-services/.

9. Disposal

Decontaminate instruments before disposal. Stainless steel instruments contain no hazardous substances and can be recycled as metal scrap. Contaminated instruments must be disposed of as clinical waste in line with local regulations.

10. Reporting incidents

Report any serious incident involving one of our instruments to BusinessMed Instruments (info@businessmedinstruments.com) and to the competent authority of the country where the incident occurred.

11. Symbols used on labels

Symbol	Meaning (ISO 15223-1)
Factory symbol (filled)	Manufacturer
`REF`	Catalogue number
`LOT`	Batch code
`NON STERILE`	Supplied non-sterile
`MD`	Medical device
Book with "i"	Consult the instructions for use
Exclamation mark in triangle	Caution
Umbrella	Keep dry
`CE`	CE marking of conformity

12. Manufacturer

BusinessMed Instruments (Manufacturer)
Jammu Road, Talwara Mughlan, Sialkot 51310, Pakistan
UK office: BusinessMed Instruments Ltd, 30 Riverhead Close, London E17 5PY, United Kingdom

Tel./WhatsApp: +92 321 8613008 · +44 7426 482104
Email: info@businessmedinstruments.com
Web: https://businessmedinstruments.com
Made in Pakistan