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CE 1639

Distributed by :
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Instructions for use INTRA HANDPIECE

Please read carefully and keep this copy for further use

Rx Only

STORZ
KARL STORZ—ENDOSKOPE

Fig. 1

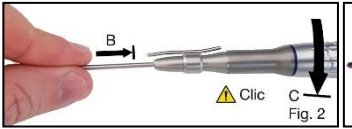

Fig. 2


Fig. 3

Fig. 4

INTRA HANDPIECES (EN)

1. TYPE

Straight and angled handpieces with external spray, for microsurgery.

2. SYMBOLS USED

CE 1639	**CE Marking** with the number of the notified body.
Rx Only	**Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.**

	**CAUTION!** Refer to the accompanying documents
	**Consult the accompanying documents**
	**Materials to be recycled** The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force.
	**Sterilizable in autoclave up to the specified temperature**

	**Cleaning in machine authorized**
	**Manufacturer**
	**Movement in the direction indicated**
	**Movement fully to the stop, in the direction indicated**

3. INTENDED USE

INTRA handpieces are intended to transmit the rotational energy from the motor to the burs for cutting and shaping bones.

4. INDICATION FOR USE
Medical device for professional use. INTRA handpieces are indicated for the drilling or shaping of bone in the head & neck/ENT (Otologic, Neurologic, Neurotologic, Sinus, Rhinologic) surgical procedures.

5. CONTRAINDICATION
None known as of today

6. PRECAUTIONS - WARNINGS

6.1. Warnings, Precautions for use
For additional information, please contact KARL STORZ at the address indicated on the front-cover of this document.

⚠ **CAUTION:**
Use adequate irrigation and avoid excessive pressure on the tool. The use of a tool without irrigation and with excessive pressure may cause an inordinate amount of heat buildup resulting in a thermal injury to tissue. See tools instruction for use for further information.

The device and its accessories should be used only by duly trained and competent medical personnel, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and the present user manual. According to these measures, the user has the following obligations:

- To only use devices in perfect working condition. In the event of irregular operation, excessive vibrations, abnormal overheating or other signs suggesting malfunctioning of the device, work must be suspended immediately. In this case, contact a repair centre approved by the legal manufacturer via KARL STORZ.
- Make sure that the device is used only for the purpose for which it is intended, protect yourself, patients and third parties from all danger and avoid contamination by the product.

The device and its accessories are designed solely for medical treatment. Any use not in conformance with the intended use is unauthorized and may prove dangerous. This medical device complies with the European legal provisions in force.

Use only original maintenance products, accessories and/or spare parts approved by the legal manufacturer. The use of other products, accessories or parts could void the guarantee and/or endanger the patient or the operator.

6.2. Environmental protection and indications for device disposal

This equipment must be recycled. The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force. The user can return the device to his distributor or call directly on a firm accredited for the treatment and recovery of this type of equipment (European directive 2012/19/UE).

7. TECHNICAL DATA

Environmental conditions:

Work	Temperature:	+10°C to +30°C (+50°F to +86°F)
	Relative humidity:	20% to 80%, including condensation
	Atmospheric pressure:	700 hPa to 1060 hPa
Transport	Temperature:	-25°C to +70°C (-13°F to +158°F)
	Relative humidity:	10% to 100%, including condensation
	Atmospheric pressure:	500 hPa to 1060 hPa
Storage	Temperature:	+10°C to +30°C (+50°F to +86°F)

	Relative humidity:	20% to 80%, including condensation
	Atmospheric pressure:	500 hPa to 1060 hPa

Noise level: <70 dBA (according to IEC 60601-1)

Size / Weight:

Handpiece reference	Designation	Bur length (mm)	Length – handpiece without bur (mm)	Handpiece weight (g)
262570	INTRA Drill Handpiece, 70 mm, angled	70	128	94
262571	INTRA Drill Handpiece, 70 mm, straight	70	111	84
262572	INTRA Drill Handpiece, 125 mm, angled	70	182	104

Period of operation: See Chap 8.7

Medical class: IIa as per 93/42 EEC directive

For further information concerning microsurgery instruments and their accessories, please contact your KARL STORZ local distributor or consult our homepage www.karlstorz.com.

8. USE

8.1. Type of coupling

The most commonly used coupling in the world as per ISO Standard 3964.

8.2. Drive

By any motor with ISO 3964, type 1, long coupling.

8.3. Type of rotary instrument

Diameter of shaft 2.35 mm (0,09 in) type 2, in accordance with ISO 1797-1. Shaft length according to table in previous page.

⚠ **CAUTION:**

Do not exceed the stipulated diameters and speeds. KARL STORZ declines all responsibility if burs of another brand are used.

Maximum speed for all KARL STORZ burs:

Diameter	Speed
< Ø 4,5 mm	80,000 rpm
Ø 5,0 mm	60,000 rpm
Ø 5,5 mm	50,000 rpm
Ø 6,0 mm	40,000 rpm
Ø 6,5 mm	30,000 rpm
Ø 7,0 mm	20,000 rpm

8.4. Insertion and removal of a rotary instrument

Turn the ring completely in the direction of arrow and insert the bur up to the thrust stop:
A: unlocking (**fig. 1**)
B: insert the bur up to the thrust stop
C: locking up to the thrust stop (**fig. 2**).

8.5. Check

Pull on the bur and check that it is correctly in position.

⚠ CAUTION:
The bur must be in perfect condition: shape, surface condition and cut. The user is fully responsible for:

- **Ensuring that the bur meets the KARL STORZ specifications, according to the burs instruction for use.**
- **Ensuring that it rotates without vibration at the speed at which it will be used.**

⚠ CAUTION:
Comply with maximum lengths by always inserting the bur as far as possible into the locking mechanism. If a bur is operated at high speeds when incorrectly mounted (i.e. not fully inserted into the locking mechanism, or being longer than the values specified above) this can cause a centrifugal force which may bend or break the bur.

⚠ CAUTION:
Do not exceed the maximum operating speed authorised by the bur manufacturer.

8.6. Precautions – warnings

⚠ CAUTION:
Before using the instrument, place it in operation at moderate speed with a tool in the bur locking mechanism for a few seconds to spread the lubricant and remove any excess.

The device must not be started without a bur inserted into the chuck.

Never mount an instrument on a rotating motor.

Never adjust the clamping/unclamping ring while the instrument is rotating, since this could damage the mechanism or destroy the motor.

Never close the chuck mechanism without the bur in place, or it may get damaged.

Comply with the recommendations for use, in accordance with the instructions of the tool manufacturer.

An inappropriate maintenance, use of inappropriate burs, or an instrument not properly closed, can cause a fast heating of the handpiece and create a risk of severe burn.

8.7. Period of operation

To avoid overheating leading to burns (temperatures between 41°C (106°F) and 48°C (118°F) on the outer surface of the handpiece), the following rules should be complied with:

a) Limit the maximum speed of rotation according to the bur diameter as indicated on the packaging and/or in the present operating instructions.
b) Do not exceed the maximum speed of rotation permissible for the handpiece.
c) Adequate irrigation is strongly recommended.

During the surgical operation, if the irrigation tube becomes clogged, use the cleaning wire and a long cleaning curette to clear (**Fig. 3**).

9. CLEANING / INSPECTION / STERILIZATION

⚠ **CAUTION:**
Do not place the handpiece in an ultrasonic bath.

⚠ **CAUTION:**
Never submerge the handpiece in physiological salt water solutions (NaCl solution), because prolonged contact may cause corrosion.

⚠ **CAUTION**
Chemical disinfection of the handpieces is not recommended due to possible negative effects on the lifetime of the devices and possible residues of disinfectants.

⚠ **CAUTION:**
These devices are delivered "non-sterile".

Before use, please comply with the present section:

- Clean, lubricate and sterilize the handpiece before first use.
- Clean, lubricate and sterilize the handpiece before each further use.
- After each use, clean and sterilize the handpiece as quickly as possible.

Precautions of use

Hospital procedures must be followed.

The universal precautions must be complied with by hospital personnel working with contaminated or potentially contaminated medical instruments.

Pointed and sharp instruments should be handled with great caution.

Agents required for cleaning:

- **Detergents**

The cleaning of the attachments has been validated using an enzymatic pH neutral detergent (Enzol®). An alkaline detergent might reduce the lifetime of the device.

Detergents should be used at the concentration, temperature and for the duration recommended by the detergent's manufacturer.

To remove physiological liquid inside the instrument or the spray tube, use "*Aquacare*" from Bien-Air Surgery.

⚠ **CAUTION:**

Do not use detergents that are corrosive or contain chlorine, acetone or bleach, aldehydic products or alcohols.

- **Lubricant:**

Exclusively use "*Lubrifluid*" from Bien-Air Surgery.

- **Brush / cleaning gun**

The brushes should be non-aggressive to avoid damaging the device. Preferably use nylon brushes with flexible or soft bristles.

Use the cleaning gun with the appropriate nozzles for the various ducts.

If you have any additional questions regarding reprocessing procedures, instructions for reusable devices etc., please contact KARL STORZ.

9.1. Point of use cleaning

⚠ CAUTION:
Initial cleaning should be performed at the point of use and as soon as possible after the completion of the surgical procedure.

⚠ CAUTION:
Point of use cleaning must be followed by manual or automatic cleaning.

This operation is important in order to facilitate subsequent cleaning stages (it prevents dirt from drying and sticking to the equipment).

As soon as you have finished using the handpiece, proceed as follows:

- Separate all components: Remove rotary instrument from the handpiece, separate external irrigation tube from the handpiece
- Separate the handpiece from the micromotor.
- Leave locking ring in open position.
- Rub the outside surface of the handpiece and of the irrigation tube with non-woven towelettes (pre-soaked in water).
- Spray the inside of the irrigation tube in the direction it is used with "*Aquacare*" or inject tap water with a syringe. Check that water can flow through the duct. If obstructed, unblock the canal.
- Ensure that the handpieces do not dry before manual or automatic cleaning by wrapping them in non-woven towelettes (pre-soaked in water)
- Manual or automatic cleaning must be done max 4h after the point of use.

9.2. Manual cleaning

- Rinse the irrigation tube under running tap water (cold, max 20°C / 68°F) and brush with nylon soft bristles for at least 15

seconds. Spray the inside of the tube for 1 second with "*Aquacare*" or inject tap water with a syringe.
- Soak the irrigation tube in lukewarm ultrasonic bath with enzymatic pH neutral detergent (for example Enzol®) for at least 3 minutes.
- Thoroughly rinse under running tap water for 10 seconds. Use a syringe with water or "*Aquacare*" to remove detergent solution from inside the tube.
- Blow dry the irrigation duct with pressurized air.

For handpieces:
- Leave the locking ring in open position.
- Rinse the handpiece under running tap water (cold, max 20°C / 68°F) and brush with nylon soft bristles for at least 30 seconds.
- Soak the handpiece in a lukewarm solution for at least 5 minutes with an enzymatic pH neutral detergent (for example Enzol®).
- Shake it inside the detergent and open and close the locking ring at least 3 times to remove air from the device and ensure the detergent solution reaching all lumens.
- Thoroughly brush the outside with nylon soft bristles for at least 30 seconds. Continue brushing until soil is no longer visible.
- Using a 3mm diameter nylon brush, thoroughly brush back and forth inside the attachment with at least 3 full movements.
- Remove the handpiece from the bath and thoroughly rinse vertically under running tap water from both ends for at least 30 seconds, opening and closing the locking ring at least 3 times. At the end leave it in open position.

Drying:
- Dry it by wiping it with a clean and dry non-woven towelette. Blow dry the inside of the attachment from each end with pressurized air.
- If the handpiece is not immediately sterilized, perform dynamic drying under

ventilation, at about ~90°C (194°F), for a minimum of 25 minutes.

Or

9.3. Automatic cleaning

Pre-cleaning:

- Leave the locking ring in open position.
- Rinse the attachment under running tap water (cold, max 20°C / 68°F) and brush the outside and all accessible lumens with nylon soft bristles (diameter of 3mm for lumens) until soil is no longer visible.
- Rinse the irrigation tubes under running tap water (cold, max 20°C / 68°F) and brush the outside with nylon soft bristles for at least 30 seconds. Continue brushing until soil is no longer visible.
- Spray (1 sec.) the inside of the irrigation tubes with "*Aquacare*" or inject tap water with a syringe.
- Pre-cleaning has to be directly followed by final automated cleaning.

Place the disassembled handpiece and irrigation tubes in the appropriate washer/disinfector basket and treat via a standard instrument washer/disinfector cycle.

Only use a validated washer/disinfector (ISO 15883).

Stages of the automatic washer / disinfector cycle:

Pre-wash:
4 minutes cold tap water.
Washing:
With enzymatic neutral pH detergent and with hot tap water, 55°C to 66°C (131°F to 149°F), for 10 minutes.
Rinsing:
Hot tap water for 3 minutes
Thermal disinfection by rinsing:
Operator is responsible for the implemented value A0 according A0 concept described in EN ISO 15883 (For example, A0 600 90°C (194°F) /1min.).
Ventilated dynamic drying:
Approx. 90°C (194°F), for at least 25 minutes.

Comments:

- Comply with the washer/disinfector loading instructions provided by the equipment's manufacturer.
- Make sure that all the instruments have been correctly attached to the baskets.
- Make sure that the instruments do not touch one another and that internal canal are properly rinsed.
- Remove the instruments from the washer or disinfector immediately after the machine stops and move on quickly to lubrication and sterilization, to avoid corrosion.

9.4. Inspection, lubrication and testing

Carefully inspect each part to make sure that all visible contamination and moisture has been removed. Check in particular that the ducts are clear. Where there is contamination, repeat the full cleaning process. Where there is moisture, use the airgun to dry it.

After each cleaning operation and before each sterilization, lubricate the handpiece with "*Lubrifluid*" from Bien-Air Surgery.

To absorb any excess lubricant, apply a cloth over the instrument's apertures.

Insert the "*Lubrifluid*" spray plastic end fitting in the rear of the handpiece's handle (**Fig. 4**) and actuate the spray for about 0.5 seconds.

Check the devices for any visible signs of deterioration or damage.

Check the presence and integrity of all visible seals.

Check the action of moving parts: Insert a clean rotary instrument onto the handpiece and close the locking ring (**Fig. 2**). Check that the rotary instrument remains in place when pulled. Holding the rotary instrument between your thumb and index finger, spin the handpiece. The handpiece shall spin freely (more than 3 turns). If it does not, there is danger of burning the patient and you should send the handpiece to your retailer or to KARL STORZ to be repaired.

Remove the rotary instrument and locking ring in the open position (

Packing for sterilization:

⚠ **CAUTION:**
Do not reassemble the handpiece with any external irrigation tubes prior to sterilization.

Separate packing: Immediately insert the handpiece in individual wrapping, such as a paper/plastic pouch or sterilization wrap for steam sterilization.

Or

Autoklavavimas p. 21.3.

d trays with defined, pre-apertures and wrap the

In the USA, FDA approved sterilization wraps, pouches or containers must be used.

9.5. Sterilization

Sterilization by vacuum steam is recommended. The following sterilization parameters, using a Pre-Vac cycle, have been validated by the legal manufacturer to provide a sterility assurance level (SAL) of 10^{-6}.

Only legally marketed, FDA cleared sterilizers, sterilization wrap/pouches, biological indicators etc. should be used by the end-user for packaging terminally sterilized devices.

Tempe-rature	132°C (269°F)	134°C[2] (273°F)	134°C[2] (273°F)	135°C (275°F)
Time	4 Min.	3 Min.	18 Min.[1]	3 Min.
Drying	30 Min.[3]			

[1] Parameters recommended by the World Health Organization for treating instruments in the event of contamination by Non-Conventional Transmissible Agents (NCTA). Parameters recommended by the legal manufacturer.

[2] Not for users in US healthcare facilities

[3] Refer to sterilizer manufacturer recommendations for drying times per load configuration.

After sterilization, let the device cool down to room temperature without forced cooling.

Since no reprocessing methods have been validated for removing transmissible spongiform encephalopathy (TSE) agents from medical devices, this device should not be used for patients with known or suspected TSE agent disease, including CJD and vCJD. The legal manufacturer recommends incinerating devices that have come into direct contact with patients suspected of or confirmed as having TSE/CJD.

The sterilizer manufacturer instructions concerning operation and load configuration should be complied with explicitly.

⚠ CAUTION:
Do not exceed a temperature of 138°C (280°F).

⚠ CAUTION:
Never rinse instruments in cold water to cool them.

9.6. Storage

The legal manufacturer strongly advises storing only sterilized devices to reduce the risks of corrosion.

Ambient conditions of storage after sterilization

- Store the equipment in a clean, dry place at ambient temperature (10–30°C (50–86°F), 20–80% humidity).
- Do not expose the equipment to direct sunlight.
- Do not expose the equipment to permanent X-ray irradiation.
- Do not store the equipment in places that could be subject to liquid splashes.
- Do not store the equipment in the following ambient conditions: - Dust - Saline or sulphurous atmosphere

- Do not store the equipment in a location where there is a risk of release of flammable gases.

Shelf life of sterilized instruments
The shelf life of stored sterilized instruments depends on the type of packaging used and the storage conditions (refer to the DIN 58953 standard, section 9, or the existing local regulations).

10.MAINTENANCE
No component of the handpiece may be changed by the user. Never disassemble the handpiece.

For all servicing and repairs, we recommend that you contact your dealer or KARL STORZ directly.

The legal manufacturer invites users to have their dynamic instruments checked or serviced at least once a year.

Hygiene
For the safety of the repair center's personnel, the instrument should be cleaned and sterilized completely before being returned for repair. If that proves impossible, for example because a disinfection or sterilization would make the instrument completely unusable, clean the instrument as carefully as possible and mark it accordingly to indicate that it has not been decontaminated.

11.MALFUNCTIONS AND ERRORS
Use the table below to solve any problem encountered. If the problem is insoluble, stop using the product and contact a repair center approved by the legal manufacturer.

Problem	Solution
There is no transmission of movement.	Check that the motor by itself operates. Check that there is a bur in the locking mechanism and that it is in “clamp” position (**Fig. 2**).
Impossible to insert the bur in the instrument	Check that the chuck mechanism is in open position (**Fig. 1**). Check that there is no part jammed inside the clamp and that the latter is clean.
	Check that the stem of the bur is in sound condition and of the correct diameter Check that the part is clean and lubricated with "*Lubrifluid*".
The bur does not rotate freely	Check that the locking mechanism ring is fully inserted (**Fig. 2**).
The instrument heats abnormally.	Check that the part has been correctly cleaned and lubricated.
Excessive vibration	Check that the handpiece is fully closed. Stop the motor and pull on the bur to check that it is correctly in position, or change/reduce the speed of rotation.




	REF 1500096	REF 1500098	REF 1000001 (10 pcs per box)	REF 1000009 (10 pcs per box)
REF 262570	X		X	X
REF 262571	X		X	X
REF 262572		X	X	X

REF 1600617 *Aquacare*
(6 pcs per box)

REF 1600064 *Lubrifluid*
(6 pcs per box)