

Instructions for Use of Rotating Kerrison Rongeurs

- **Always** When inserting a new shaft into a new handle, make sure the handle is in the closed position and the moving handle moves freely otherwise the new force open mechanism will not function.
- Do not strike an instrument on a hard surface to remove tissue or cartilage from jaws.
- **Always** use an appropriate instrument for larger jobs to avoid fracturing the instrument. Do not grab something larger than what the jaws of the instrument were designed to accommodate.

These Instructions for Use (IFU) are valid for the reusable surgical instruments with item numbers:

404-605, 404-606, 404-607, 404-6071, 404-6072, 404-6073, 404-6074, 404-6075, 404-6081, 404-6082, 404-6084, 404-6085, 404-607, 404-6076, 404-6077, 404-6078, 404-6079, 404-6080, 404-6086, 404-6087, 404-6088, 404-6089, 404-6090, 404-6061B, 404-6062B, 404-6063B, 404-6063EB, 404-6082C, 404-60825E, 404-6083B, 404-6083E, 404-606B, 404-606SB



CAUTION:

Federal law restricts these devices to sale by or on the order of a physician.

Intended Use

Rongeurs are manually operated instruments indicated for grasping, holding, cutting, or biting bone cartilage and tissue structures during surgery.

Device Description

These are reusable instruments made of high-grade surgical stainless steel that utilize articulating jaws to sequester and cut both bone and soft tissue. The devices usually rely on splayed, articulating handles to operate and sometimes employ springs to hold the jaws open. Jaws are usually articulated by means of interacting sliding shaft segments. Rongeurs and punches are available in differing lengths, cutting widths, and style variations. The selection of the appropriate model is the option and responsibility of the physician or surgeon.

Squeeze the handles together to cut. Remove gross debris from surgical instruments with a disposable towel and sterile water routinely during the procedure to prevent drying of residues.

Indications

Use the instrument only in accordance with its Intended Use (see above).

Contraindications

The instruments shall not be used for anything other than their Intended Use.

Pre-Caution

- Check that screws and pivot pin on instruments are intact and check functionality after ultrasonic cleaning.
- Closely inspect rongeur at distal tip, where damage most often occurs, significantly reducing the instrument's ability to cut. If damage to cutting surface is discovered, schedule the instrument to be repaired immediately and discontinue use.
- Rongeurs are supplied non-sterile and must be cleaned, lubricated and sterilized prior to use.
- Carefully inspect all springs and screws for cracks and debris, and check functionality of instrument.

Precleaning

Remove gross debris from surgical instruments with a lap sponge and sterile water routinely during procedure to prevent drying on of blood and body fluids, etc.

For best results, and to prolong the life of the instrument, begin cleaning and sterilization process immediately after use.

Manual Decontamination

1. Maintain moisture: Immediately after surgical procedure, place instruments in an instrument tray/container and cover with a towel moistened with sterile water. Foam, spray, or gel products specifically intended for use with surgical instruments are available to keep soil moist. Rinse foam, spray, or gel products from instruments with distilled water prior to enzymatic soak.
2. Enzymatic soak: Immerse fully opened and/or disassembled instruments in an enzymatic solution, specific for use with surgical instruments. Prepare solution and use per enzyme manufacturer's recommendations or instructions for correct dilution, temperature, and soak time.
3. Rinse: Remove from enzymatic soak after time period recommended by enzymatic manufacturer and rinse thoroughly with lukewarm distilled water.
4. Cleaning instruments: Choose a cleaning solution appropriate for surgical instruments and follow the manufacturer's instructions for use.
5. Rinse: Thoroughly rinse instruments with distilled water and wipe with a clean, soft cloth.
6. Ultrasonic Cleaning and Rinsing: Follow recommendations of ultrasonic manufacturer regarding cycle times, detergents, proper placement of instrument tray, and conditioning of cleaning solution.
7. FINAL RINSE with distilled pyrogen-free water (preferred).
8. Visual Inspection and Instrument Set Assembly: Visually inspect instrument for cleanliness and ensure all parts are in proper working order.
9. Lubricate: The use of a water-soluble instrument lubricant that is compatible with pre-vacuum steam sterilization is recommended before instruments are sterilized.
10. Drying: Before instruments are wrapped for sterilization, they must be thoroughly dry. Prepare instrument sets for sterilization in a pre-vacuum steam sterilization.

Mechanical Decontamination

Before using automatic washer:

1. Follow steps 1-3 of Manual Decontamination above to maintain moisture, perform enzymatic soak, and rinse.
2. Open or disassemble instruments as appropriate so that bind holes can drain.
3. Avoid excessive loading of washing trays.
4. Use appropriate instrument carriers only.
5. Take special care that instrument tips do not get stuck in the mesh when placing instruments into and removing from the baskets.
6. Avoid placing heavy instruments on delicate instruments.
7. Make sure that loading doesn't prevent water jets from reaching the load directly.
8. Use a validated washer/disinfector intended for use in automated cleaning processes and follow the minimum cycle parameters contained in Table 1 (below).
9. Follow the manufacturer's specifications when using automatic washers to process general surgical instrumentation.
10. Remove instruments from automatic washer.
11. At the end of the cleaning, follow steps 7-10 of Manual Decontamination above to perform instrument final rinse, visual inspection for any visible soil (in particular the joints, springs, and holes), lubrication, and drying before terminal sterilization.

Sterilization

Recommended steam sterilization parameters to achieve Sterility Assurance Level of 10⁻⁶:

Sterilizer: Pre-vacuum (wrapped)

Temperature: 132°C (270°F)

Exposure Time: 4 minutes

Minimum Drying Time: 20 minutes

Drying

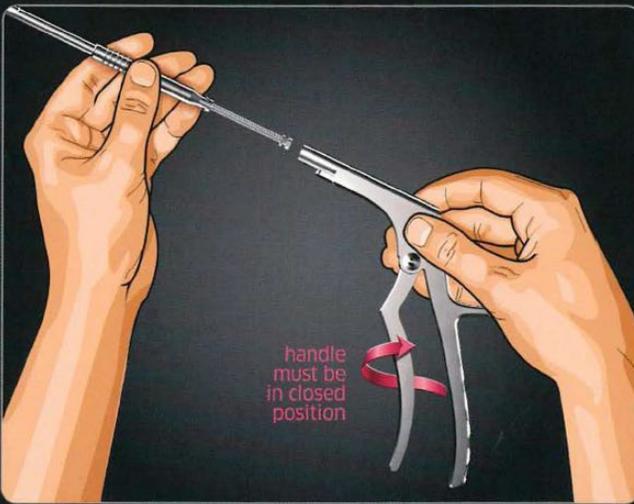
If device is still wet after automated cleaning cycle, thoroughly dry the device using a clean lint-free cloth.

Table 1: Automated cleaning cycle parameters

Cycle	Time	Minimum Temperature	Type of Detergent /Water
Pre-Cleaning	2 minutes	Cold, <45°C / 113°F	Tap water
Cleaning	10 minutes	Heated, 55°C / 131°F	Nedisher® Mediclean Forte, 0,5-2%
Rinse	2 minutes	Cold	Tap water
Terminal rinse	5 minutes	Heated, 90°C / 194°F	Demineralized water
Dry	25 minutes	Heated, >50°C / 122°F	N/A

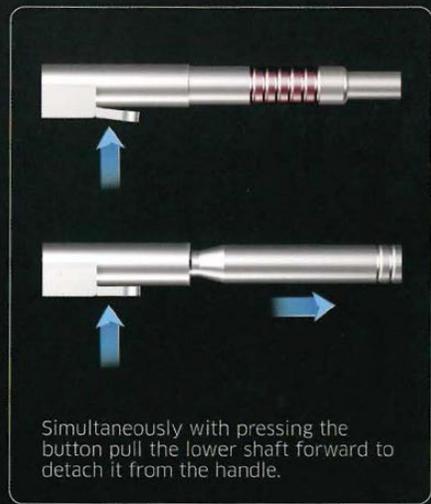
Sontec instruments are guaranteed to be free of defects regarding materials and workmanship. Any Sontec instrument that is determined to be defective will be replaced or repaired at our discretion. **Instruments not properly cared for, used for purposes not intended, or used beyond the design capacity will NOT be covered.** Our liability under this guarantee is limited to the repair or replacement of the defective merchandise.

INSERTING SHAFT



handle must be in closed position

RELEASING SHAFT



Simultaneously with pressing the button pull the lower shaft forward to detach it from the handle.

IMPORTANT:

WHEN INSERTING NEW SHAFT INTO NEW HANDLE, YOU HAVE TO MAKE SURE THAT HANDLE IS IN **CLOSED POSITION** AND MOVING HANDLE FREE TO MOVE. OTHERWISE, THE NEW FORCE-OPEN MECHANISM WILL NOT FUNCTION!

Click Kerrison punches are suitable for all kinds of shafts: Straight, Bayonet, Curved up and down. You do not need to keep a large stock of Kerrisons, only the shafts are necessary.

This new kind of Kerrison's approach, besides significant financial savings simplifies the entire working process. Your productivity will not be affected by a very short training period. The costs of migration to this new product are very

low and the positive results are almost immediately visible.

For detailed information regarding training and available additional instruction see the contacts on the back cover of this brochure.

EXTREMELY EASY to Clean

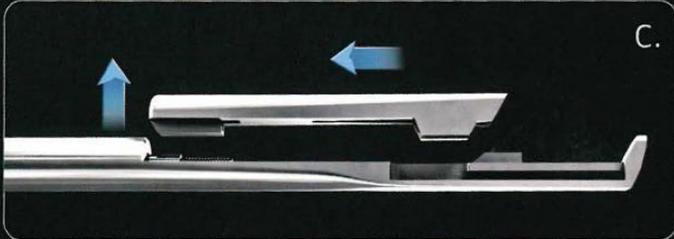
Our tests have shown that personnel, of all profiles and education levels, quickly learns the technique of disassembling and reassembling the Click Kerrison punches



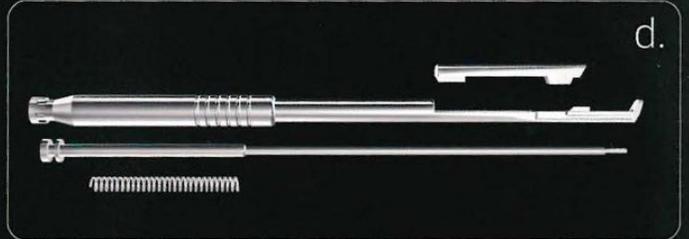
a.



b.



c.



d.

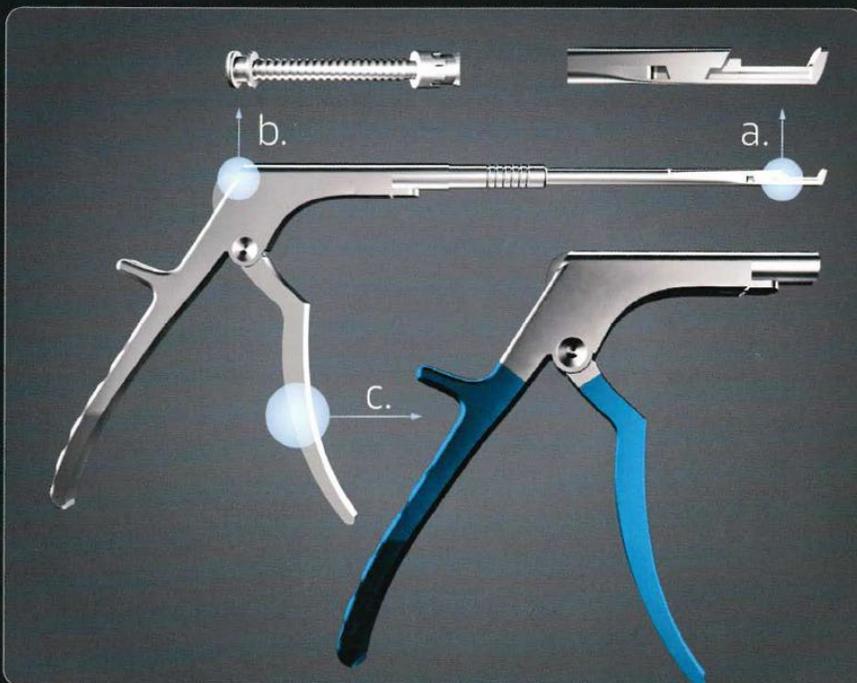
a Once the shaft is pulled out you can easily recognize the 4 parts on it that must be dismantled for sterilization.

b The shaft is secured by the spring system. After it is unscrewed you can easily disunite the lower and upper shaft.

c The shafts can not be separated while the upper shaft is in forward position. Slide back the upper shaft towards the edge on the lower shaft and pull it upwards. Then you can lift the upper shaft out of the T-groove.

d When the sterilization process is completed the parts are easily reassembled according to the previous instructions.

TECHNOLOGY. SIMPLICITY. SOLUTION.



a Small handle, but at the same time 14mm mouth opening. Perfect for surgeons, who do not like the large Kerrison handles, but do not want to miss the advantages of a large mouth opening.

b The advanced spring system rules out any problems with springs slipping off or breaking as well as gloves getting caught in the spring. Surgeons are also enabled a better view on the operating field during surgery.

c To ensure even better performance new Smart Handle Technology is also available providing a better and softer grip (for more info see the contacts on the back cover of this brochure).

SMART HANDLE: color code grip
Color coding option is available in different colors, all according to your needs.