Ultrasonic cleaning system for the medical products

- Implants of metal and ceramic
- Medical instruments, endoscopes and accessories

www.elma-germany.com
Manufacturing process with cleaning steps for metal implants of Ti, Co/Cr/Mo, 316L, 316LN, Ta

Mould blanks (HIP), rolled or forged

Rough cleaning filings, cooling lubricants

Cut blanks

Milling, turning, drilling, thread cutting of implantate

Rough cleaning
Working residues, lubricants, oils, greases

Implantate: slide-grinding & blasting or polishing

Final cleaning, if necessary
Finger prints, dust, lapping- and polishing agents

Modification of surface (if required)
e.g. coating, passivation

Additional cleaning (if required)
Finger prints, dust

Packaging

Can be carried out in one cleaning machine
Manufacturing process with cleaning steps for ceramic implants

1. Formed green parts (Al2O3, ZrO2)
   - Sintering
   - Working: Milling, drilling

2. Rough cleaning
   - Milling residues, emulsion

3. (Slide) - grinding, polishing

4. Fine cleaning or final cleaning (if required)
   - Lapping- and polishing agent residues

5. Crack test (if required)

6. Final cleaning (if required)
   - Colouring agent, ...

Manufacturing process with cleaning steps for medical instruments

1. Turning, milling, grinding

2. Intermediate cleaning
   - Cleaning of cooling lubricants, filings, metallic parts

3. Polishing, lapping, finegrinding

4. Final cleaning
   - Cleaning of polishing- and lapping agents, dust. Finger prints.
Standard products for rough-, fine- and final cleaning in the manufacturing process

**Flex 1 und 2**
**X-tra 250 / 550 / 800 / 1200 / 1600**

Ultrasonic and rinsing equipments for the cleaning of implants, medical instruments and endoscopes with water-based cleaners and following rinsing for small throughput. Ultrasonic available in two multi frequency versions 25/45 kHz, 35/130 kHz.

Accessories: Agitation, pump filter unit for bath care.

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**X-tra Line**
**250 / 550 / 800 / 1200 / 1600**

Modular system with standard devices for the cleaning of implants, medical instruments and endoscopes for small to medium throughput. From manual devices to fully automatic versions with transport robot.

**Advantages:**
- Proved industrial series devices in different sizes and versions.
- From the single device to the automated equipment.
- Elma X-tra line can be extended step by step according to your needs and available budget.
- Modular system for different cleaning requirements.
- Extensive range of options and peripheral devices.
- Short delivery time.
- Plug & Clean.
- Choice of different cleaning programs in connection with transport system.
- Interchangeable devices and options for later modification and upgrade of cleaning requirements possible.
- Upgrade of the modules and devices is possible at any time.

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**STC/MTC 50-200**

Fully automatic standard equipments in different sizes and versions for the cleaning of implants, medical instruments and endoscopes for a high throughput. Process steps free selectable and with extensive options. Modular system with standard devices.

**Advantages:**
- Modular system depending on the individual process requirements.
- Ultrasonic equipment with multi frequency technology for the different sensitive products.
- Flexible integration into the production process (in line solution).
- Process related flexibility of cleaning line and application.
- Well proven components.
- Graphically designed control system.
- Process control production for constant quality.
- Lower investment costs through standardization.
- Adjustment of investment costs to the shortened product lifecycles.
Typical equipment versions for the manufacturing of metal implants

**STC100-6-WLT-F-LRS2**

Cleaning product: Knee implants  
Material: Femur, CrCoMo alloy, titanium alloy, VA, plastic material  
Pollution: Manufacturing residues after pre-cleaning, polishing pastes  
Cleaning result: Final cleaning before sterilisation and packaging  
Cleaning chemistry: elma clean 112, elma clean 212  
Process: Cleaning-(Ultrasound)-Cleaning-(Ultrasound)-Rinsing-(Ultrasound)-Rinsing-(Ultrasound)-Rinsing-(Ultrasound)  
Size of batch: 250 x 510 x 100 mm (W x L x H)  
Throughput: 12 batches / h  
Periphery: Automatic loading conveyer  
Machine speciality: Optional swivel device for assembly parts with blind holes at the robot, transport device in clean room, controled branch before the clean room.

**X-tra-Line 550/4-WLT-R**

Cleaning product: Hip-joint implants (socket joint)  
Material: Ceramic  
Pollution: Working residues from polishing as dust of diamond and ceramic  
Cleaning result: Final cleaning before inspection  
Cleaning chemistry: elma clean 225E/I  
Fixed cycle: 3 – 5 min  
Process: Cleaning-(Ultrasound)-Rinsing-(Ultrasound)-DI-(Ultrasound)-Drying  
Periphery: Filter pump-aggregate for tank, clean water circulation equipment. Loading and unloading conveyer.

Typical equipment versions for the manufacturing of ceramic implants

**X-tra-Line 550/4-WLT-R**

Cleaning product: Joint implants  
Material: Ceramic  
Pollution: Finger prints, dust, polishing residues, residues of dye penetrant test (crack test)  
Cleaning result: Free from residue and dry, visual control by microscope  
Cleaning chemistry: elma clean agent 225  
Process: Cleaning-(Ultrasound)-Rinsing-(Ultrasound)-DI-(Ultrasound)-Drying  
Periphery: Dosing, device, filter pump, FFU, clean water circulation equipment elmapur 600 Loading and unloading conveyer in connection with clean room lock  
Machine speciality: Validation for medical products, swinging of the parts to be cleaned.

**MTC50/7-WLT**

Cleaning product: Joint implants  
Material: Ceramic  
Pollution: Finger prints, dust, polishing residues, residues of dye penetrant test (crack test)  
Cleaning result: Free from residue and dry, visual control by microscope  
Cleaning chemistry: elma clean agent 225  
Process: Cleaning-(Ultrasound)-Rinsing-(Ultrasound)-DI-(Ultrasound)-Drying  
Periphery: Dosing, device, filter pump, FFU, clean water circulation equipment elmapur 600 Loading and unloading conveyer in connection with clean room lock  
Machine speciality: Validation for medical products, swinging of the parts to be cleaned.
Typical equipment versions for the cleaning and passivation of metal implants

**X-tra 800/5-WLT-R**

Type: Robot device for the cleaning and passivation
Cleaning product: Implants
Material: Titanium alloys, VA
Pollution: Polishing pastes, oils, greases, Corund
Cleaning result: Final cleaning/passivation
Cleaning chemistry: elma clean 112, elma clean 212
For passivation: elma clean 115C
Process: Cleaning (Ultrasound)-passivation (Ultrasound)-Rinsing-
Rinsing (Di)-Drying
Periphery: Oil separator, pump filter, clean water circulation equipment
Machine speciality: Device can be used for cleaning (fixed cycle: 5 min) or for cleaning and passivating (Fixed cycle: 10 min)

**STC50-7-WLT-LRS1**

Type: Robot device for cleaning and passivation
Cleaning product: Medical implants
Material: Titanium or stainless steel
Pollution: Polishing pastes, finger prints, working residues
Cleaning result: Final cleaning before assembly and packaging
Process: Cleaning (Ultrasound)-rinsing-passivation (Ultrasound)-
Rinsing (Di)-Dryng
Cleaning chemistry: elma clean 112, elma clean 212
For passivation: elma clean 115C
Periphery: Tunnel dryer, automatic dosing, pump filter

**x-tra 550/8-WLTZ-M**

Type: Fully automatic robot device for the final cleaning
Cleaning product: Implants and instruments
Material: Stainless steel, titanium
Pollution: After the mechanic test, finger prints, particles
Process: Cleanig (US), Rinsing, Passivation (US), Rinsing,
Rinsing DI (US), Rinsing DI, Drying
Cleaning chemistry: elma clean 112, elma clean 212
Passivation: elma clean 115C
Periphery: Automatic dosing, PF
Machine speciality: Device can only be used for cleaning (fixed cycle: 5 min) or for cleaning and passivating (fixed cycle: 10 min)
Typical equipment versions for rough and fine cleaning for the manufacturing of medical instruments, endoscopes and accessories

**x-tra-550/4-WLT-M**

Cleaning product: Medical instruments  
Material: Titanium, stainless steel, aluminium  
Pollution: Working emulsion  
Cleaning result: Final cleaning before sterilisation and packaging  
Cleaning chemistry: elma clean 225E/I  
Process: Cleaning - rinsing - passivation - DI - Drying  
Periphery: Oil separator, filter pump, clean water circulation equipment  
Machine speciality: Manual device with control, also available as fully automated robot device

**Accessories**

Besides the cleaning devices and equipments Elma offers a wide range of accessories.

- Water treatment plant for the generation of softened city water, reverse osmosis water resp. pure water for the circulation in different classes of performances of 100 - 2400 l/h.
- Pump filter units for the continuous bath care of cleaning and rinsing tanks.
- Laminar flow modules for the generation of clean room conditions within closed cleaning equipments.

**Reference list**

- Aesculap-Werke  
  Tuttlingen, Germany  
  Rudischhauser  
  Tuttlingen, Germany
- Bayer AG  
  Leverkusen, Germany  
  S + N Richards  
  Tuttlingen, Germany
- Ciba-Geigy  
  Basel, Switzerland  
  Siemens UB med  
  Erlangen, Germany
- Fehling  
  Karlstein, Germany  
  Steiner  
  Engen, Germany
- Henke-Saas-Wolf  
  Tuttlingen, Germany  
  Storz  
  Tuttlingen, Germany
- Hoffmann La Roche  
  Grenzach-Wyhlen, Germany  
  Wenzler  
  Tuttlingen, Germany
- Keramed  
  Moersdorf, Germany  
  Ceramtec  
  Markedreitz, Germany
- Kreidler  
  Tuttlingen, Germany  
  Digitana  
  Horgen, Switzerland
- Link  
  Norderstedt, Germany  
  Prototype  
  Freiburg, Germany
- O. Leibinger  
  Mülheim-Stetten, Germany  
  JRI Limited  
  Sheffield, UK
- R. Martin  
  Tuttlingen, Germany  
  Tuttlingen, Germany
Elma Reinigungschemie für die Medizin

<table>
<thead>
<tr>
<th>Contamination</th>
<th>Processing steps before and after cleaning</th>
<th>Stainless steel, Titanium</th>
<th>Aluminum alloys</th>
<th>Ceramics</th>
<th>Plastic materials</th>
<th>Product (short name)</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residues of mechanical treatments: emulsions, oils, greases; abrasives, mass finishing &amp; polishing agents.</td>
<td>After or between steps of mechanical treatments like turning, milling, drilling, grinding or polishing.</td>
<td>+</td>
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<td>+</td>
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<td>elma clean 110 (EC 110)</td>
<td>Concentrate for the ultrasonic cleaning, NaOH-based, emulsifying.</td>
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<td>+</td>
<td>+</td>
<td></td>
<td>elma clean 112 (EC 112) + elma clean 212 (EC 212)</td>
<td>Alkaline builder- and surfactant-concentrate for the ultrasonic cleaning, KOH-based, demulsifying.</td>
</tr>
</tbody>
</table>

Precleaning and intermediate cleaning

| Polishing abrasives and mass finishing agents, fingerprints, dust and particles. | After polishing, mass finishing, blasting and before packing up. | + | + |  |  | elma clean 110 (EC 110) | Concentrate for the ultrasonic cleaning, NaOH-based, emulsifying. |
| Mass finishing agents, fingerprints, dust and particles. | After mass finishing, blasting and before packing up. | + | + |  |  | elma clean 260 dip&splash (EC 260d&s) | Concentrate for the ultrasonic immersion cleaning and for cleaning by splashing, removes lime soaps, demulsifying. |
| Mass finishing agents, fingerprints, dust and particles. | After mass finishing, blasting and before packing up. | + | + |  |  | elma clean 300 (EC 300) | Concentrate for the ultrasonic cleaning, KOH-based, emulsifying. |
| Polishing abrasives and mass finishing agents, fingerprints, dust and particles. | 2nd cleaning step after alkaline cleaning (after polishing, mass finishing, blasting), before packing up. | + | + |  |  | elma clean 115C (EC 115C) | Concentrate for the ultrasonic cleaning, based on citric acid, emulsifying. |

Final or finest cleaning, respectively

| Iron ions in the surface of stainless steel parts (passivating layer) - they are a risk of corrosion. | After cleaning and before packing up. | + |  |  | elma clean 115C (EC 115C) | Dissolves iron ions out of the oxidic surface layer by forming soluble iron compounds. |

Passivation of stainless steel surfaces

We about us

Highly specialized, and yet innovative in multiple ways – this is ELMA, a company which has successfully been on the market with their ultrasonic technology for more than 50 years now. ELMA started in 1948 with only 2 people who had an idea for a totally new watch cleaning machine. They kept looking for the perfect cleaning technology which eventually led them to try ultrasound.

Constant research and permanent technical improvement of the products in the ultrasonic and process technology department have always been the core competence of the company. The product range contains a large number of serial units, modular cleaning lines and special customer-made cleaning installations. Cleaning chemicals, developed, tested and produced in our own chemical laboratory round off the ELMA product range and help to solve even the most difficult cleaning jobs in various business sectors.

ELMA are exporters of customized state-of-the-art technology into more than 70 countries all over the world, distributing their products to watchmakers and jewellers, to dental and research laboratories, to companies in the medical and optics sector and to industrial businesses. You can find ELMA products on more than 100 international trade shows. Numerous distributors around the world recommend the ELMA technology to their customers and rely on the ELMA quality standard „Made in Germany“.

There is a staff of more than 200 people working in the research and production departments at three company sites in Singen in the South of Germany.

With ELMA, quality and service enjoy top priority! In addition to the main business with ultrasonic technology, we have been highly competent as a partner for watchmakers and jewellers, looking back on a long tradition in this sector. There are special machines for all purposes around the valuable watches and jewellery: for manufacturing, for testing, for servicing and for cleaning and the ELMA engineers are constantly working on the development and design of new machines.