	<b>Reprocessing instructions</b>		
	<b>Instruction for reprocessing of surgical instruments</b>		
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**Manufacturer:** implantcast GmbH

**Procedure:** Instrument Cleaning

**Product(s):**

This cleaning information is applicable for all instruments for re-use, supplied by **implantcast GmbH** which are solid instruments, instruments with a simple hinge construction and / or assembled instrument systems.

<b>WARNING</b>	<p><i>This instruments are supplied <b>non sterile</b>.</i></p> <p>Before each application, all the instruments must be cleaned, disinfected and sterilized. This is valid in particular for the first use after distribution. Effective cleaning and disinfection is an indispensable requirement for an effective sterilization.</p> <p>When using the instrumentation please consider the following:</p> <ul style="list-style-type: none"> <li>➤ The contaminated and unused instruments must be stored in different trays.</li> <li>➤ Consequently a stronger contamination of the unused instruments is avoided.</li> <li>➤ It is not allowed to clean the instruments in the tray during machine cleaning.</li> <li>➤ Before replacing the contaminated instruments in the tray, they must be cleaned and disinfected.</li> <li>➤ The complete tray is to be sterilized.</li> </ul> <p><b>Please consider the elements below as part of your responsibility for sterility of the instruments during application:</b></p> <ul style="list-style-type: none"> <li>- <b>In principle only device and product-specifically validated processes may be used for the cleaning, disinfection and sterilization;</b></li> <li>- <b>Used devices (disinfector / sterilizer) have to be washed, checked and examined regularly;</b></li> <li>- <b>Suitable proven parameters are to be adhered to in each process.</b></li> </ul> <p><b>Special attention</b> should be paid to the <b>cleaning</b> of long narrow cannula and cavities in instruments.</p> <p>The application of ultrasonic cleaners is only allowed as supporting measure for instruments <b>made of metal</b>.</p> <p>Please consider additionally valid national/regional legislation and guidelines as well as the hygiene regulations of the medical surgery and/or the hospital. This is valid in particular for the different standards for an effective inactivation of prions (not valid for USA).</p> <p><b>Please consider further the specific references to the individual instruments in the document "specific information ".</b></p>
<b>Effect of cleaning and decontamination on the life span of instruments</b>	<p>Repetitive cleaning and decontamination of surgical instruments will not influence the life span of the instruments. The span of use will normally only be affected by wear and damage during use. The use of damaged and/or dirty instruments lies with the responsibility of the user.</p>

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<b>Instructions:</b>	
<b>Storage and Transport</b>	<p>Instruments should be kept in the dedicated containers, and positioned on the trays, as indicated by the tray layout photos for storage and transport. The containers have to be kept closed or filled with distilled water or covered with damp towels, to prevent further surface drying.</p> <p>Cleaning the instruments must take place within a maximum of <b>2 hours</b> after contamination. All instruments are considered as contaminated which were used during the operation.</p>
<b>Basics for Cleaning</b>	<p>For cleaning and disinfection an automated procedure (washer-disinfector) should be used preferably. A manual procedure, even applying an ultrasonic cleaner, should only be used if a machine procedure is unavailable. A manual procedure is less effective and reproducible.</p> <p>Pre-cleaning must be done in any case!</p>
<b>Preparation for Cleaning</b>	<p>Check whether the instrument should be disassembled before cleaning.</p> <p>It is not allowed to clean the instruments in the tray.</p> <p>The instructions for cleaning that comes with the instrument trays should be read and followed.</p> <p>The disassembly instructions contain steps that should be followed to disassemble <u>and reassemble</u> the instrument.</p> <p>In case of disassembly care should be taken not to mix up any of the components.</p> <p><b><u>Attention:</u></b> For an accurate cleaning process all hinged instruments should be in a wide open position during the full cycle of cleaning. Any special instructions, when applicable should be followed.</p>
<b>Manual Pre-cleaning</b>	<p>Directly after application of the instruments (within a maximum of 2 hours) coarse contamination must be removed.</p> <p>When selecting the detergent, it must be ensured,</p> <ul style="list-style-type: none"> <li>- that it is fundamentally suitable for cleaning of instruments made of stainless steel and plastic.</li> <li>- that the chemicals used are compatible with the instruments (see also chapter "<u>Material Resistance</u>").</li> </ul> <p>In addition to the protection of the personnel disinfection can take place. The disinfectant should be aldehyde-free to avoid fixation of blood stains. Likewise it must possess a tested effectiveness, e.g. VAH / DGHM or FDA approval/clearance resp. CE certification. Further it must be suitable for the disinfection of the instruments (see also chapter "<u>Material Resistance</u>").</p> <p><b>The concentrations and exposure times of the detergents and disinfectants must be adhered to the specifications defined by the manufacturer.</b></p> <p>Specifications and additional instructions can be found in document "specific information".</p> <ul style="list-style-type: none"> <li>- Immerse the instrument into a cleaning solution for the exposure time defined by</li> </ul>
Procedure	







# Reprocessing instructions

## Instruction for reprocessing of surgical instruments

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Method 2:  
Cleaning w/o ultrasonic

contamination left, you have to repeat the procedure (beginning with point 1). Continue with the disinfection process.

1. Disassemble the instruments, if possible. See also "additional information" and product-specific "disassembling information".
2. Put the instruments into the cleaning solution for the given exposure time. Make sure they are sufficiently covered. Pay attention that the instruments don't touch each other and no air becomes trapped. Subsequently, gently clean the instruments with soft straight and circular brushes.

If applicable:

At the beginning and the end of the exposure time rinse all lumens of the instruments at **least five times** with cleaning solution using a disposable syringe (minimum capacity depends on the magnitude of instruments: 10ml to 100ml) or, if appropriate, a rinsing adapter. If the instruments have large lumens or cavities, it is necessary to rinse them **at least three times** with cleaning solution.

Moving parts must be moved back and forth **at least five times**.

3. Take the instruments out of the cleaning solution and rinse them **at least three times for 1 minute** under running water.

If applicable:

Rinse all lumens of the instruments at least **five times** with cleaning solution using a disposable syringe (minimum capacity depends on magnitude of the instruments: 10ml to 100ml) or, if appropriate, a rinsing adapter. If the instruments have large lumens or cavities, it is necessary to rinse them **at least three times** under running water.

4. Inspect the instruments (see also chapter "service" and "inspection"). If there any contamination left, you have to repeat the procedure (beginning with point 1). Continue with the disinfection process.

Disinfection  
(after method 1/ 2)

1. Immerse the disassembled, cleaned and checked instruments into the disinfectant for the given exposure time. Make sure they are sufficiently covered. Pay attention that the instruments don't touch each other and no air becomes trapped.

Moving parts have to be moved back and forth at least five times.

If applicable:

Rinse all lumens of the instruments at least five times with disinfectant using a disposable syringe (minimum capacity depends on magnitude of instruments: 10ml to 100ml) or, if appropriate, a rinsing adapter. If the instruments have large lumens or cavities, it is necessary to rinse them at least three times with disinfectant.

2. Take the instruments out of the disinfectant and rinse them at least three times for 1 minute under running water.

If applicable:

Rinse all lumens of the instruments at least five times use a disposable syringe (minimum capacity depends on magnitude of the instruments: 10ml to 100ml), or if necessary, a rinse adapter. If the instruments have large lumens or cavities, it is necessary to rinse them at least three times under running water.

3. Dry the instruments with filtered air by blowing off out the remaining.
4. Package the instruments as soon as possible (see also chapter "Packaging"). If necessary, the instruments have to be additionally dried before packaging in a "clean room".


Drying  
Packaging

The fundamental suitability of an effective manual cleaning and disinfection is proven by an independent accredited and recognized test laboratory (§15(5) MPG), using the detergent Cidezyme (Johnson & Johnson Medical, Norderstedt) and the disinfectant Cidex OPA (Johnson & Johnson Medical, Norderstedt). The above-mentioned process has been considered.

<p><b>Service</b></p>	<p>Check all instruments after cleaning and disinfection for corrosion, damaged surfaces, flaking and contamination. You have to separate damaged instruments out. Instruments which are still contaminated have to be cleaned and disinfected again.</p>
<p><b>Inspection</b></p>	<p>Mount all disassembled instruments (see also document "specific information").</p> <p>If feasible do not use instrument oil. If the usage is necessary, e.g. instruments with joint function or tribological pairing, please consider that the instrument oil must be suitable for steam sterilization. Use only white mineral oil and ensure that it is temperature resistant for the used sterilization temperature. Consider that the white mineral oil is biocompatible. Notice that only the required placements of the instruments will be oiled a little. The efficiency of sterilization can be impaired by the use of oil. Therefore a specific validation is required in responsibility of the user.</p> <p>If instruments belong together to a system, it is necessary to check all parts of the system together.</p>
<p><b>Packaging</b></p>	<p>Position the cleaned and disinfected instruments in the appropriate instrument tray.</p> <p>Please put the instrument tray into the sterilization container. The sterilization container has to meet following requirements:</p> <ul style="list-style-type: none"> <li>- EN ISO / ANSI AAMI ISO 11607 (for USA: with FDA clearance)</li> <li>- The sterilization container has to be adapted for steam sterilization by fractionated vacuum process. Likewise the container must be temperature resistant at least up to 142°C (288°F) and also transparent for steam.</li> <li>- The instruments and sterilization container must be protected against mechanical damage.</li> <li>- The sterilization container must have a regular maintenance; the interval is indicated by manufacturer.</li> </ul> <p>Please consider that the mounted one and two-story sterilization containers have a permissible total weight of 10kg (22 lb) and the mounted three-story sterilization containers have a permissible total weight of 9,6kg (21,2 lb)!</p>
<p><b>Product Marking</b></p>	<p>During the inspection of the instruments the product marking/s should be legible.</p>
<p><b>Sterilization</b></p> <p>Steam sterilization</p>	<p>For sterilization only the following kinds of sterilization processes are allowed. Other kinds of sterilization not allowed!</p> <ul style="list-style-type: none"> <li>- Fractionated vacuum process with adequate drying of the products</li> <li>- Steam sterilizer according to EN 13060 resp. EN 285 (for USA: ANSI AAMI ST79, with FDA clearance)</li> <li>- A validated process according to EN ISO 17665 with implemented commissioning (IQ / OQ) and also product-specific evaluation (PQ).</li> <li>- A maximum sterilization temperature of 138°C in addition of the tolerances according to EN ISO / ANSI AAMI 17665 s allowed.</li> <li>- Exposure time: By using fractionated vacuum process at a sterilization temperature of 132°C/134°C (270°F) for at least 4min<sup>23</sup></li> <li>- Drying time: 25 minutes (minimum / in chamber)</li> </ul>

<sup>2</sup> resp. 18 min for inactivation of prions (not valid for USA).

<sup>3</sup> HTM 2010 part 2 is fulfilled; 134°C / minimum holding time: 3 minutes

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<p>Expeditious sterilization</p> <p>Additional kinds of sterilization</p>	<p>Expeditious sterilization is in principle <b>not allowed</b>.</p> <p>Hot-air sterilization, radiation sterilization, formaldehyde sterilization and also plasma sterilization are <b>not allowed</b>.</p> <p>The fundamental suitability an effective steam sterilization is proven by an independent accredited and recognized test laboratory (§15(5) MPG), using the HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum procedure. The typical conditions in clinics and the above-mentioned process have been considered.</p>
<b>Storage</b>	<p>Storage areas for medical products should be in a clean and dust free environment.</p>
<p><b>Additional information</b></p> <p>Material Resistance</p> <p>Sterilization</p>	<p>Please consider the selection of detergents and disinfectant do not have the following ingredients present:</p> <ul style="list-style-type: none"> <li>- organic, mineral and oxidizing acid (minimal acceptable pH-value 7)</li> <li>- intense alkaline solution (maximum acceptable pH-value 11); neutral / enzymatic or light alkaline detergents are recommended</li> <li>- organic solution (e.g. alcohol, ether, ketone, benzene)</li> <li>- oxidizing agent (e.g. hydrogen peroxide)</li> <li>- halogens (e.g. chlorine, iodine, bromine)</li> <li>- aromatic hydrocarbons / halogenated hydrocarbons</li> </ul> <p>For cleaning the instruments and instrument trays do not use a metal brush or steel wool!</p> <p>The application of ultrasonic cleaners is only allowed as supporting measure for instruments <b>made of metal</b>.</p> <p>Do not use rinse agents or acidic neutralizers.</p> <p>No instruments, instrument trays or instrument containers should be exposed to a <b>temperature exceeding 142°C (288°F)</b>.</p> <p>The total weight must be observed, if more than one instrument trays are sterilized in one sterilization cycle.</p>
<b>Exclusion of liability</b>	<p>The use of the instruments for any other purpose is <b>not allowed</b>. Ignoring these regulations excludes any liability.</p>



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