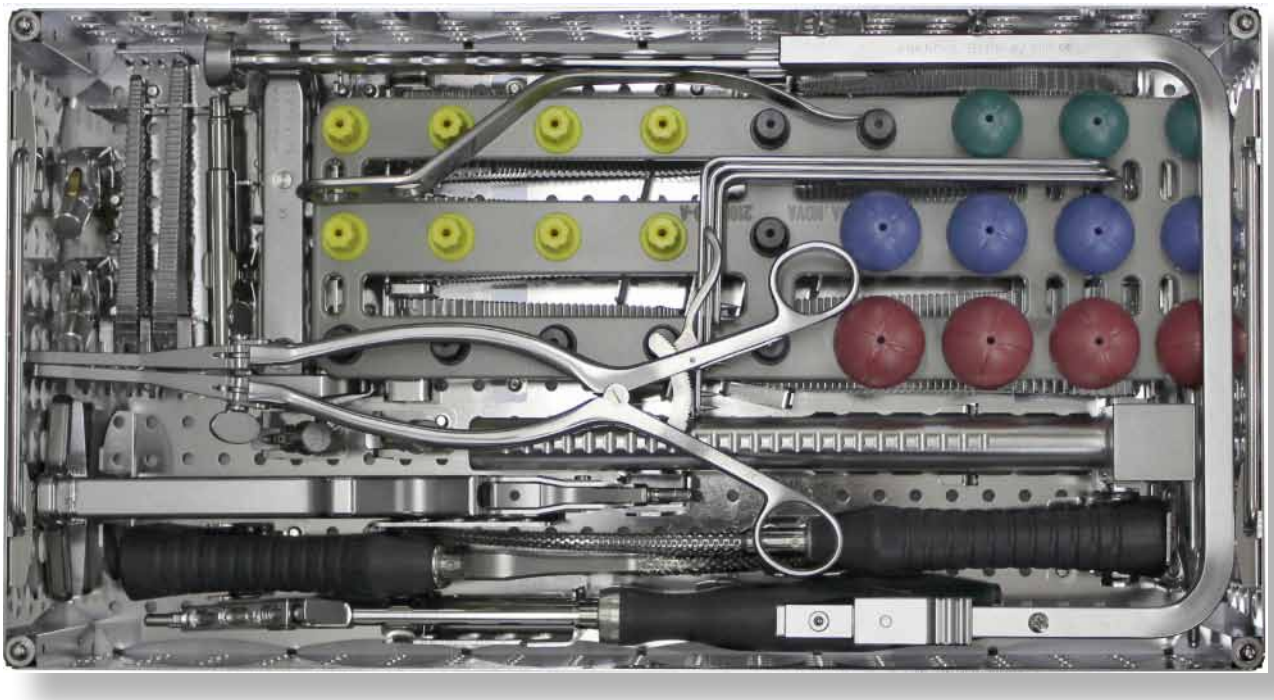
ImplanTec

PROCESSING MANUAL



MANUAL
FOR INSTRUMENT PROCESSING

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This sterilisation brochure applies for the reusable surgically-invasive products and surgical instruments manufactured by ImplanTec and belonging to the ANA.NOVA®, CCG®, and Halcor systems.

RISK ASSESSMENT AND CLASSIFICATION

All instruments from ImplanTec GmbH are to be regarded as critical A or critical B.

GENERAL WARNING INFORMATION

Processes
The sterilisation processes described in this brochure must be adhered to. The hospital must ensure a safe sterilisation process.

Handling Instruments
Instrument trays and instruments must be handled separately when sterilising.

Aids
For ultrasonic sterilisation, contaminated cleaning agents should be replaced prior to use, otherwise sterilisation is not effective.

Limitations with Reprocessing
The end of the product life is normally defined by wear and damage during use. Reprocessing has comparably minimal impacts on the product life of instruments.

Interval
The maximum interval between the use and reprocessing of the instruments may not exceed six hours.

Safety Guidelines – Process Chemicals
The safety guidelines of the utilised process chemicals must be followed.

MANUAL FOR INSTRUMENT PROCESSING

The following instructions were validated for the preparation of a medical product for its reuse. The processor is responsible for ensuring that the actually conducted processing with utilised equipment, materials, and personnel achieves the desired outcomes in the processing device.
Validation and routines monitoring of the process are normally required for this.

Detailed information about the detachable instruments can be found in the surgical technique for the respective system.

1. GUIDELINES IN PROCESSING

- Avoid extensive waiting times during processing to minimize the risk of corrosion.
- To the extent possible, the instruments must be disassembled into individual parts. See the respective operation technology or the packing slip included with the delivery for detailed information.
- The instruments must be placed on instrument trays suitable for machine washing and rinsing.
- Joint instruments must be opened to minimize overlapping surfaces.

2. PREPARATION IN THE OPERATING ROOM

The first steps of proper processing start in the operating room.

The following must be considered when setting the instruments aside: The instruments can be damaged by improperly "dropping" the instruments down (e.g. deformations or damage to instruments – particularly the tips). Thus, it is necessary to ensure that the instruments are properly set aside and the instrument trays are not overfilled.

- Residues, such as blood, tissue, caustic pharmaceuticals, etc. should be removed as best as possible prior to being put aside.
- If loading is not possible, it is necessary to ensure that the instruments are particularly thoroughly removed of residues and rinsed off with demineralised water until they are visually clean. As an aid, a soft brush (bottleneck brush, etc.…) can be used. The instruments can optionally be pre-cleaned by means of an ultrasonic bath until they are visually clean. Detachable instruments must already be taken apart prior to washing.
- Do not use fixatives (no aldehydes, no alcohols).
- Cutting and sharp instruments must be secured; cannulated must be rinsed.
- A suitable brush must be used to clean tubes and blind holes so that every spot is reached.
- The maximum interval between the use and reprocessing of the instruments may not exceed six hours.

These measures are intended to prevent blood residues or contaminants from drying up!

3. STERILISATION AND DISINFECTION

Manual Pre-Sterilisation

Holes, grooves, and joint surfaces require special attention during manual pre-sterilisation.

- Instruments are generally cleared of coarse contaminants by means of sterilisation agents and disinfectants (demineralised water) with the help of a soft brush or an ultrasonic bath. To prevent denaturation, the temperature may NOT exceed 43° C.
- Do not use fixatives (no aldehydes, no alcohols).
- Inspect all tubes, blind holes, etc. for visible contamination; if necessary, clean manually.
- All manipulable spherical heads are removed from the holder prior to sterilisation and the blind hole is rinsed by means of demineralised water.
- Thorough cleaning is assisted through the additional use of an ultrasonic cleaning stage.

Recommended for critical A instruments and **absolutely required for critical B.**

Machine Sterilisation and Disinfection

- Processes, for which sterilisation is done separately from the disinfection, are to be preferred. Conducting the machine processing thermally is recommended.
- The instruments are properly placed into the appropriate mesh trays of the washer-disinfector and sterilised and disinfected by a validated standard machine cycle.
- To ensure effective sterilisation, reamers must be inserted in an inclined position and manipulable spherical heads must be removed from the holder.
- The instruments must be taken out of the washer-disinfector immediately after the program has ended, as corrosion may occur due to residual moisture as a result of remaining in the closed machine.

Necessary for instruments with the **critical A and critical B rating!**

Machine sterilisation and disinfection should be done with a process validated according to relevant regulations in a washer-disinfector in compliance with ÖNORM EN ISO 15883 -1 and -2 preferably using (mildly) alkaline detergents.

Program:

Phase	H20 type	Temp. (C°)	Time (min.)	Disp. temp. (C°)	Dispensing (ml/L)
Pre-rinsing	Demineralised	Cold	≥2	-	-
Washing	Demineralised	55+/-5	≥7	35	4-10
Rinsing I	Demineralised	Cold	≥1	-	-
Rinsing II	Demineralised	Cold	≥1	-	-
Disinfection	Demineralised	93+/-3	≥5	-	-
Drying	Demineralised	110	15	-	-

Standard process 55° C / 10 min. / 0.6% determined and the key points 50° C / 10 min. / 0.4% (minimum program) and 60° C / 10 min. / 1% (maximum program) checked. Dispensing when using neodisher® MediClean forte.

4. IMPORTANT HANDLING GUIDELINES

- Proper loading allowing for rinsing is required for effective machine processing.
- Instruments with hollow spaces must also be completely cleaned on the inside.
- Large instruments must be placed on the mesh tray in such a way that they do not impede the cleaning of other instruments due to “obstructed areas”.
- The mesh trays may not be overloaded so that the instruments are properly washed.

The residual concentration of the detergents in the last process water may be no more than 250 ppm or 25 µS/cm when using neodisher® MediClean forte. Should this be exceeded, the sterilisation/disinfection process must be repeated.

5. DRYING

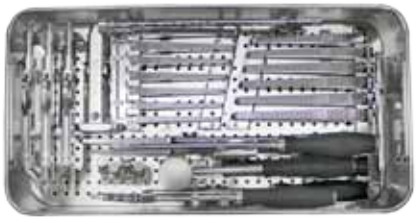
- Through the washer-disinfector or other suitable measure, it is necessary to ensure that the instruments are sufficiently dry.
- To prevent the occurrence of water spots, a final rinsing with demineralised water must be conducted.
- No drying agents should be used.

6. INSPECTION AND CARE

Adequate cleanliness is a basic requirement for successful sterilisation!

- The instruments must be checked for potential residues by means of a macroscopic visual inspection and cleaned again if necessary. If residual contamination is discovered, the wash/disinfection process must be repeated. In the case of damage, the instruments must be replaced!
- With instruments that are assembled into larger units, it is necessary to check if the individual components can be easily assembled.
- Polymers used in instrument sets can be sterilised with moist heat. Polymer materials have a limited life. Should the polymer surfaces become “chalky” and/or have excessive damage (e.g. white coloring due to micro cracking, flaking), they should be replaced.
- A visual inspection for completeness and/or wear of the instruments must be conducted.
- The mobility of moveable parts must be checked (e.g. hinge joints, locks, twisting parts, sliding parts).
- Long and narrow instruments must be checked for distortion. Bent rotating instruments must be replaced!
- The instruments are maintenance-free. Additional lubricants are not necessary.
- Cutting instruments (e.g. drills) must be checked for sharpness and damage.

7. PREPARATION FOR STERILISATION



- All instruments must be put into the appropriate tray prior to sterilisation.
- All instruments that are assembled into larger units must be reassembled to such an extent as designed in the respective tray prior to sterilisation. See the respective operation technology or the packing slip included in the delivery for detailed information.

8. PACKAGING

- Sterile goods must be appropriately packaged so that recontamination does not occur during subsequent work steps.
- Drying is assisted by placing the trays into a towel within the sterilisation container or the outer paper packaging.

9. STERILISATION

The manuals for the respective sterilisers must be followed during sterilisation.
The following parameters were validated by ImplanTec according to the requirements of sterilisation standard, EN ISO 17665, for the first and subsequent sterilisation. Fractionated steam sterilisation is recommended as a standard method:

Cycle type	Temperature	Pressure	Sterilisation duration	Drying time
Fract. vacuum	134°	3 bar	5 minutes	25 minutes

ImplanTec recommends sterilisation according to the validated method listed above. If other methods are applied by the user, they must be validated by the user according to the EN ISO 17665-1. Final responsibility for the validation of the sterilisation techniques and sterilisation equipment is that of the user.

10. STORAGE

- Instruments must be stored dry and in suitable storage containers.
- After sterilisation, the sterilised goods must be stored in a dry and dust-free environment in a bacteria-proof sterilised goods bag or container. Temperature fluctuations must be avoided to prevent condensation build-up and thus corrosion damage.
- The maximum storage time depends on various factors, such as packaging, storage methods, environmental conditions, and handling. The user must define a maximum storage time for sterile products until use himself. The products must be used during this time or potentially processed (sterilised) once again.

11. RENTAL EQUIPMENT

For products, which are delivered in the form of rental equipment and returned to the manufacturer, all cleaning steps must take place to the same extent, e.g. with instruments, which are not returned. In the case of a return delivery, a confirmation of the processing must be included.

GENERAL INFORMATION

1. DETERGENTS AND DISINFECTANTS

- The use of hard water must be avoided. To prevent a depositing of minerals on the instruments, demineralised water should always be used for the first as well as for the last washing.

- Cleaning action treatment agents with or without an antimicrobial effect and/or enzymes, which have no protein-fixation effect, must be used for sterilisation and disinfection. The manufacturer information in regard to the concentration and exposure time, and potentially the addition of cleaning intensifiers must be observed. The validation of ImplanTec GmbH occurred with neodisher® MediClean forte.

- Stainless steel instruments may under no circumstances be placed in a physiological saline solution (NaCl solution), as prolonged contact leads to pitting and crevice corrosion.

- In the case of wet disposal, the instruments are preferably placed in a solution of a combined detergent and disinfectant, which has no protein-fixation effect. Disinfectants containing aldehydes must be avoided, as they have a protein-fixation effect.

- When using alkaline detergents, only approved detergents may be used exclusively for sterilising surgical instruments. The instruments must then be immediately treated with a suitable neutralizing agent and subsequently thoroughly rinsed with demineralised water. In the case of machine sterilisation, the neutralization is already included in the sterilisation program.

- Color-anodized aluminum components may lose their color when using machine sterilisation methods, though without impacting the functionality of the instrument. When using pH-neutral cleaners and through the use of demineralised water for subsequent rinsing (even with thermal disinfection), color anodizing can be processed with the remaining goods to be sterilised.

- If powdery products are used, the powder must be completely dissolved prior to use in order to prevent discoloring or corrosion of the instruments.

- Please also observe the statutory regulations applicable in your country as well as the hygiene regulations of the hospital. This applies in particular for the various provisions with respect to an effective inactivation of prions. ImplanTec recommends discarding the products in the event that the products come into contact with elusive pathogens (or the suspicion thereof), such as the variation of the Creutzfeldt-Jakob disease.

2. AIDS

When choosing the utilised detergent, disinfectant, and devices, for all steps ensure that:

- They are suitable for the intended application (e.g. sterilisation, disinfection, ultrasonic cleaning of medical products),
- The detergent and disinfectant are free of aldehyde (otherwise fixation of blood contaminants),
- They have a tested effectiveness (e.g. VAH/DGHM or FDA approval or CE marking),
- The detergents and disinfectants are suitable for the products and compatible with the products,
- The manufacturer information, e.g. in relation to concentration, exposure time, and temperature, are complied with.

- In hospitals with a central sterilised goods supply department, a transport of the contaminated medical products occurs in closed systems from the operating room to the central sterilised goods supply department. Whenever possible, dry disposal is to be preferred.

- A requirement for effective machine processing is proper loading of mesh trays, screen inserts, holders, etc. allowing for rinsing. Jointed instruments must be inserted opened.

- The use of lint-free, soft cotton/polyester/blended fabric towels, plastic brushes or cleaning nozzles is recommended. Metal brushes, coarse "scouring agents" and the use of excessive force must be avoided. Fleece may lead to insufficient drying.

- Drying with compressed air is to be preferred over any other drying method, as it is particularly gentle and effective.

- All packaging materials, which are used for moist sterilisation, must correspond to applicable European standards (standard series EN 868).

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