PRODUCTION PLAN

Implants and prosthesis parts are made using raw materials, tested and certified for medical use, after that the production device master file has been realized.
During the working from machine, the pieces are controlled to identify possible discrepancies in comparison to the drawings and the functional coupling tests are made.
The production lot goes to the control department, the pieces are washed and then submitted to piece-by-piece dimensional and functional controls so to assure the 100% quality.
Based on special customers' inquiries, **Tecom Implantology** can supply specific surface treatments thanks to qualified external suppliers.

SANDBLAST TREATMENT
The sandblast is made using a low contamination mixture, completely eliminable with the next wash.

CONTROLS
Each production lot foresees the production of sandblasted sheets on which a control is made to check that the ruggedness is in conformity with the data of the quality plan.

WASH AFTER SANDBLAST
Implants are inserted into containers, divided by diameter and length and submitted to wash and drying.

COVERING EQUIPMENTS
When required by the features, implants are supplied with masks to protect the area not to be covered, then they are assembled on the multiple mandrel, taking care of the mask-holding and the correct positioning. In order to guarantee the maximum precision, the positioning of the masks is made by using the microscope.

CONTROLS
For each expansion of 29 pieces the thickness of 3 implants in prefixed positions is controlled by a micrometer 0-25.
The values registered before and after the covering are mentioned in a thickness data sheet.
In case of not conformity, as established by the quality control, sheets and traction drops in Ti-6Al-4V are covered and sent to the laboratory which makes the necessary measures to check that the covering features are within the acceptance values. A 100% visual control on the pieces to be checked:
- correct covering delimitation
- uniformity of the covering
- absence of inclusions and/or impurities
- absence of breakings

PROCEDURES TO DECONTAMINE DENTAL IMPLANTS

The decontamination treatment has the purpose to clean the screws surface in the best way. The aim of every cleaning surface process is to get the maximum cleaning level in accordance with the atmosphere in which it is. The process must eliminate all the pollution elements accidentally entered during the work. The treatment is preceded by a washes series, with the purpose to eliminate the raw contamination. The typical washing procedures use ultrasonic baths and a series of solvents/grease washers.

Prodotto da:

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All the operations which foresee the implants handling must be made using free of powder gloves, single use.
The packing of the decontaminated pieces for an eventual conservation or transport must be made in containers which do not cause contamination. Aluminium sheets are suitable, normally used to transport and conservation of samples for the surface analysis.

Working procedures:

The work foresees the following steps:
1. Positioning of the samples in glass containers.
2. First washing cycle, treatment of 2,5 minutes
3. Water washing
4. Second washing cycle, as point 1
5. Double water wash
6. Treatment with basic solution of bicarbonate (4%) for 1 minute
7. Water washing
8. Acid passivity
9. Triple water wash
10. Double acetone wash
11. Dry in fan-stove at 60° C
12. Packing in aluminium sheets

The steps from 1 to 10 are made at room temperature, in a controlled room.
General conditions. The use of free of powder gloves. For the washings, use of glass beker.
The concentrations of the components are valued by using micro-pipettes.
The treatment is made lot by lot. Maximum 40 units per tray are positioned on a polystyrene tray, covered by an aluminium sheet.

STERILIZATION PLAN (external supplier)
A competitive service must be of high quality, able to match more and more demanding market requirements, and able to assure a careful execution of the entire sterilization process.

Through a specific checking quality program we can satisfy any kind of request, offering many services as:
- sterilization at BETA rays (accelerated electrons);
- service of confirmation of irradiation BETA processes;
- packaging systems;
- checked pollution areas;
- decontamination and washing processes;
- special processes on demand;
- Microbiological, biochemical, chemical analysis services.

The irradiation with accelerated electrons is made by upgraded systems, totally computerized, and with the following features: Energy 10MeVm power 25KW, box with dimensions max. 80x80x120 and min.20x20x20.
The material management, since its arrival, is computerized and complete of measure controls with Certificate release.

The electrons accelerated system assures an irradiation from 0,1 to 100 kGy, depending by the specific needs.

Each work is by an external qualified supplier, certified as per TUV, ISO 9001 – EN46001 dispositions and approved by many other audits of several bureaus like IMQ, ISS, CERIMEDICA, MED CERT, BVQI.
In order to guarantee an analytic control and a complete certification of the sterilization and treatment of the material, Tecom Implantology can, on demand, supply laboratory services as: microbiological analysis, chemical analysis, resistance of the material analysis, measures analysis, radiometry analysis, product sterilization analysis, control raw materials contamination, residual of ethylene oxide in the materials, residuals of cloridrine and ethylenic glycol, measure on irradiated materials, mechanical and resistance tests of the material, confirmation of the sterilization processes, confirmation of the packaging systems.

DOCUMENTS SUPPLIED
In order to guarantee all the steps above mentioned, we can supply the following documentation:
1 test report
2 certificate L.O.P.
3 schedule thickness values
The documents at the points 1 and 2 are sent to the clients together with the pieces, the ones at the point 3 are filed in the certificates archive.

DOCUMENTS OF REFERENCE (on demand)
- standard execution tests for fillings
- standard operative instructions to receipt and release of biomedical parts
- standard operative methods of control in entry of the parts
- standard operative methods washing parts
- procedure to produce coverings on parts for biomedical use
- standard sandblasting on biomedical parts
- control method of the percentage of porosity and granulometry of the not-melted particles and the covering pollution
- ASTM F1580: standard specification for Titanium and Titanium 6% aluminium 4% Vanadium Alloy Powders for Coatings of Surgical Implants.

What above mentioned in reference to the Certifications ISO 9002/94 STANDARD and EN46002 of the supplier company.

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