Large joint implants production plant: organization and prospectives

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OOO «ZAO TREK-E Composite»

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Project background

Currently there is no large-scale production of large joint implants in Russia.

In 2017 more than 90 thousand hip joint replacement operations were performed in Russia. The current demand is no less than 160 thousand operations.

Hip joint market volume in Russia is about 10 billion rubles a year.

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Project idea

Preparing and launching a large-scale full-cycle high-tech production of licensed medical orthopedic products.

Ensuring the conformity of characteristics and quality of products to the level of the best modern products produced abroad.

The project combines the expertise and knowledge of ООО «ЗАО ТРЕК-Е Композит» in serial production of licensed medical equipment and scientific and technological competencies of ROSATOM State Corporation.

Financial support:
Ministry of Industrial and Trade development of RF
Russian Fund for the industrial development
Moscow Government, Department of Science, Industrial Policy and Entrepreneurship.

SHORT-TERM OBJECTIVES OF THE PROJECT:

Creation of coverings and implants with programmable properties: biocompatibility, durability, aseptic stability, biological activity in the conditions of their use for orthopedics, surgery and others directions of medicine.
Product samples – hip joint implants
designed by OOO «ZAO TREK-E Composite»

Porous coating

Basic tool kit:
- Fitting ball
- Drift pin
- End mill
- Ball impactor
- Cavity impactor
- Handle
- Impactor-extractor
- Inlay impactor
- Graver
- Spheric mills
- Special wrench

Material for tool manufacturing
- Steel 12X18H10T GOST 5632, тв. 35-38 HRC
- Steel 40Х13 ГОСТ 5632, тв. 46-48 HRC
- Steel 95X18H10T GOST 5632, тв. 56-58 HRC
- Fluoroplastic А TV 6-05-832
- Textolite ПТ-40 copr 1 ГОСТ 5
The general approach - putting the bioactive agents capable to influence osteogenesis in the field of the bone and implantation interface:
- adhesive molecules;
- morphogenetic proteins;
- various bioactive agents.

PROGRAMMABLE PROPERTIES of BIOACTIVE AGENTS - a solution of the problem of achievement of long stabilization after endoprosthesis replacement operation.

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3-LAYERED IMPLANT COATING

1\textsuperscript{st} layer has a density of 93-95% and provides a high adhesion of the coating to the material of the implant;
2\textsuperscript{nd} layer has a density of 80-90% and allows for the forced penetration and circulation of bone fluid in the pores of this layer,
3\textsuperscript{rd} layer has a density of 60-75% and creates a basis for the growth of bone tissue and its life support system. This layer is characterized by the formation of developed longitudinal (up to 1-3 mm) and transverse pores with a diameter from 250 to 400-450 µm.

Three-layer coating is formed in one spraying operation with reciprocating motion of the plasma torch with a programmed speed.

The thickness of successively applied layers is related as 1:3:8.
The first layer is 40-50 µm thick, the second is 120-150 µm, the third 800-1200 µm.
MANUFACTURING CYCLE OF THE HIP JOINT IMPLANT FEMORAL COMPONENT

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Implant production plant
(25 thousand sets per 1 year)

Lathe machining system CTX 310
Milling machining system DMU 50
Milling machining system DMC 635V
Electrospark discharge machine Sodick VL 400Q
Porous coating machine

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Core indicators

<table>
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<tr>
<th>Implant production level per year, pcs</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
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<td></td>
<td>3 450</td>
<td>10 000</td>
<td>15 000</td>
<td>20 000</td>
<td>25 000</td>
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- **The price** is lower by 25–40% when compared to foreign counterparts (depends on the model).
- **Russian budget savings**: the cost of operations is dramatically reduced.
- **Increase in tax revenues by** 500 million roubles in the course of 2017-2021.
- No less than **85 high production workplaces**
- **Multiplicative effect**: increase in revenue of domestic suppliers of materials and components by more than 1 billion roubles in the course of 2017-2021.

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Thank You for attention!

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