MANAGEMENT OF INNOVATIONS IN LIFE CYCLE OF SURGICAL INSTRUMENTS

Joanna BARTNICKA

Summary: The considerations about developing a model of innovations management in life cycle of surgical instruments was described in the article. The proposed research aims at gaining a new knowledge in the discipline of Production Engineering in the field of innovation management methodology in a participatory approach to product life cycle, the specific example of surgical instruments, including search a methodology to assess the effectiveness of the life cycle of the product in terms of: knowledge management and capacity to pro-innovation activities.

Keywords: life cycle management, surgical instruments, participatory design, knowledge management, innovations.

1. Introduction

The article aims at presenting the main assumptions of research on developing a methodological basis for knowledge-based innovation management in the *life cycle of surgical instruments* (LC-SI) including participatory approaches.

The proposed studies are part of the demands set out by the Polish Academy of Sciences and included in the expert, etitled: *Stan i perspektywy badań naukowych w obszarze inżynierii produkcji w Polsce* (*Status and Prospects of Research in the Area of Production Engineering in Poland* - translation mine). The need for research on the problems manufacturing support has been highlighted. The problems, next to the construction and manufacturing processes, are a fundamental, however still unrecognized in scentific area, the pillar of the innovative economy. Among the supported manufactoring problems increasing intangible costs should be mentioned associated with the acquisition and processing of information required for design, manufacturing, operating and marketing processes, especially of such information, which can be translated into value creation and innovation management.

A branch in which innovation is one of the most important elements affecting the viability and profitability is the medical sector together with the manufacture of surgical instruments. New surgical techniques, greater awareness of ergonomics and end-users requirements are forcing manufacturers to take action pro-innovation-oriented search mode participatory design solutions and new approaches to design based on the so-called "customization", i.e. adapting the product to the needs of the end-users. One should bear in mind that the tools must be adjusted to the needs and predispositions of the surgeon as well as of the patient. These predispositions are related to the psychosomatic features in particular.

Taking into consideration such an approach as well as the need to improve the rationality and effectiveness of the product life cycle, it is necessary to determine the methodological basis of studying the flow of information, knowledge transfer and communication between participants in the cycle, including end-users. Developing a model

of innovation management will enable providing a basis for practical application by the company by identifying mechanisms to support transfer of knowledge and a way of communication with the given, often dispersed participants in the cycle, indicating factors, including the technologies and methods of determining the formation of innovation in the cycle, from designing the product to its exploitation; thus, making a framework for creating innovation and building competitive advantage.

The results of previous studies conducted at the Institute of Production Engineering [1-3] seem to confirm the validity of the assumptions of the research. This is because they indicated the following problem areas:

- the lack of adjustment of technical-usable and ergonomic parameters of surgical instruments to the features and abilities of the users (surgeons, scrub nurses),
- high level of surgical instruments differentiation resulting from variety of surgical operations. Every type of surgical operation requires application of other instrumentation set (e.g. arthroplasty of knee joint requires other set of instrumentation than arthroplasty of hip joint, shoulder joint, elbow joint etc.),
- complex structure of surgical instruments requiring performance of assembly and disassembly activities during the surgical operation, very often in stress-inducing conditions,
- the lack of adjustment of the content of user guide to the needs and perception capabilities of users,
- the user guide is in English only,
- the insufficient number of training in area of using the surgical instruments (a low amount of training courses is the results of notations in a SIWZ documentation (specification of the crucial conditions of the order),
- limited possibility of exercising using the surgical instruments by staff in view of sterilization procedures,
- the gaps or lack of knowledge transfer between participants in the product life cycle,
- frequent exchange of equipment resulting from short fitness for use lasting usually one year. Due to specificity of public procurement process the new set may vary from the previous one because of changing the manufacturer whose product was chosen by tender.

With respect to the issues identified above, it appears advisable to implement of such innovations in the product life cycle, which would support the process of effective creating the skills of medical staff in the area of using and handling of surgical instruments. The development of supporting tools for the process could be created at an early stage of the cycle through the preparation of training materials based on computer simulations. Such materials, in turn, could also be the base for the development of marketing innovations based on virtual technologies. The realization of such assumptions forces to undertake the research on modelling the transfer of knowledge and ways of communication throughout the product life cycle.

Another aspect of this problem is a new approach of health care units to the public procurement issues and elaborating the SIWZ. The purchase process should be so redesigned and the way of elaborating the SIWZ should be so changed, that the new-purchased equipment would be accordance with not only the lowest price, but also with the needs of end-users, i.e. medical staff and patients.

2. Product life cycle management – a literature review

The problem of innovation management in such specific area, which is the life cycle of surgical instruments, **is a new problem** not only in Poland but in the world. It is reflected in the literature reports, pointing to the deficit of research in the field of medical device development [4]. The available literature sources from the area of designing medical devices highlight the need to consider the ergonomic needs of future users, substantive environmental conditions and patient safety in the process [5], the standards of designing based on the safety using the medical devices as well as human factor design approach [6-10].

The literature highlights the need to developing the mechanisms which are verified in practice and the methods of cooperation between the industry and the health sector in the area of creating innovative products taking into account ergonomic principles as a priority [4]. One of the symptoms of such an ergonomic approach is designing with using electromyography method (EMG). In the research conducted by Wu et al. [11] the EMG method was used to assessment of muscle tension during the surgical activities with using the four variants of one type of surgical instrument (a scalpel) and the choice of the optimal variant. But, apart from the EMG method it was used in addition: a questionnaire and a scientific staging with the left and right handed users who used the each scalpels variant and special phantoms.

It should be noted that the research concerned the instruments that have already been produced and used in practice, and such results can be used as a guide for designing the instruments in the future. The research challenge is to develop a method of validation of surgical instruments in the design, not in the exploitation phase.

Generally, the subject matter of the product development methodology is present in the literature. There are indicated four kinds of product modelling methodologies: solid product modelling, feature-based product modelling, knowledge-based product modelling and integrated product modelling but the perspectives are oriented in research into inter alia how to use the knowledge to support product design [11].

According to Buckle P. et al. it is necessary to encourage the industry to an user-oriented design. The encouragement must go hand in hand with building robust scientific methods, which support innovative designing development, and increasing competitiveness [5].

The way of customization the product to the end-user needs can be treated individually by designing and producing a product for a specific individual user. Such approach is important and has already been implemented inter alia in the prothesis industry [12, 13].

We can find in the literature many articles describing researches related with product lifecycle management, as a management system of interrelated entities and processes. It is noted, that in order to manage life cycle products and for actors involved in the life cycle to collaborate efficiently, life cycle products should first be modelled. It was conducted a research under the 6th Framework Programme, Project Promise - Product Lifecycle Management and Information Tracking Using Smart Embedded Systems, which goal was to develop an appropriate technology of products, so-called Embedded Devices Information, which enable to collect information throughout the life cycle and thus to optimize the cycle. The attention was drawn to a number of traditional modelling methods, classifying them into two categories: enterprise modelling methodologies and product life cycle modelling [14]. The proposed new approach describes the behaviour of whole product life cycle objects: product, process and resource. The models need to be designed

in such a way so that they are capable of showing various perspectives relevant to the situation concerned, thus permitting alternative product configurations and their development possibilities to be evaluated [14]. The presented model of the product life cycle relates to the products with a high degree of modularity. Hence, a large attention was dedicated to the issues of optimization of the manufacturing and recycling processes.

Meanwhile, the proposed in the article researches, aims at drawing the attention to the issue of adjustment the product to the end-user needs and the disclosure of innovative activities in this area. It is justified by the fact that the selection of materials and method of the disposal is standardized in the medical sector. The mentioned customization of product is based on the mechanisms of knowledge management. Such an issue in the creation of innovative products is described in the literature [15, 16].

In the next approach to the subject matter it is indicated a new paradigm of life product management in industrial manufacturing which is: in order to add value and maximize utilization, products are linked in the manufacturer's network from beginning to end. Such paradigm needs new methods, tools and technologies related on information and communications systems [17]. An example of a system, which fulfils the mentioned assumptions of the paradigm is KCModel (knowledge configuration manager) proposed by Badin et al. dedicated to knowledge configuration management applied to design projects [18]. The KCModel ensures the coherence of information e.g. the same parameter value is used in several expert models, through several product design activities in a collaborative engineering context.

Much research are also dedicated to the particular aspects of the methodology for knowledge management in product life cycle. The research undertaken in this area are related to supporting knowledge management about product based on methods of documenting the life of the product for the automation of the design process [19-21]; the participatory design methods [22, 23], including methods based on web technologies [24] as well as on contextual inquiry method/contextual observation (CI) [4] or on boundary objects [25]. The difficulties in the area of acquisition of usable knowledge in the design process of medical devices were identified. These difficulties largely stem from a lack of the effective mechanisms of obtaining the implicit and tacit knowledge [26] which concern the difficulties with articulate the manners of operations, especially on the line the medical staff - the patient.

However, it was indicated that the participatory approach to design, and thus, the gaining difficult to codify expertise, can be supported by heuristic methods, such as focus group [23] or delphi technique [27].

As the initial research showed, a crucial element of an innovative approach to product lifecycle management is to predict the respective life cycle phases, taking into account such aspects as: technical-usable, economic, safety and ergonomics, and also reaction and anticipation of the consequences in case of any changes in the cycle. The effectiveness of these measures depends largely on the degree of cooperation and linkages between the R&D sector, which develops innovative methods of product lifecycle management, the industry sector, which initiates and implements the solutions and the end-users, who indicate specific needs. The way to strengthen the relationships is to increase and improve the transfer of knowledge which is capable on the one hand to develop innovative solutions, and on the other hand, to absorb them. Such an improvement of transfer of knowledge takes place in particular by increasing the capacity of communication between the participants of the cycle. At present, the participants of various stages of product life cycle use a language, which is appropriate to their specialization, confronting technical language with the

language of financial or marketing, or, in this case, of end-users - the medical language. Such situation causes the communication gaps, which concern of both the cooperating autonomous companies and even the units from one entity [28].

The need for improvement of communication forms in the product life cycle is also indicated in the recent literature, including in [29].

3. Methodology

The literature indicates, that product life cycle is divided in three main stages [30]:

- 1st stage - Begin-of-life (BOL), which encompasses product design to production stage;
- 2nd stage - Middle-of-Life (MOL), which encompasses usage and maintenance stage;
- 3rd stage - End-of-Life (EOL), which encompasses the disposal/recycle stage.

Based on the basic structure of the product life cycle the decomposition of the specific phases was performed (Fig. 1). The decomposition has become, in turn, the basis for the formulation of research methodology aimed at developing a model of innovation management in the life cycle of surgical instruments.

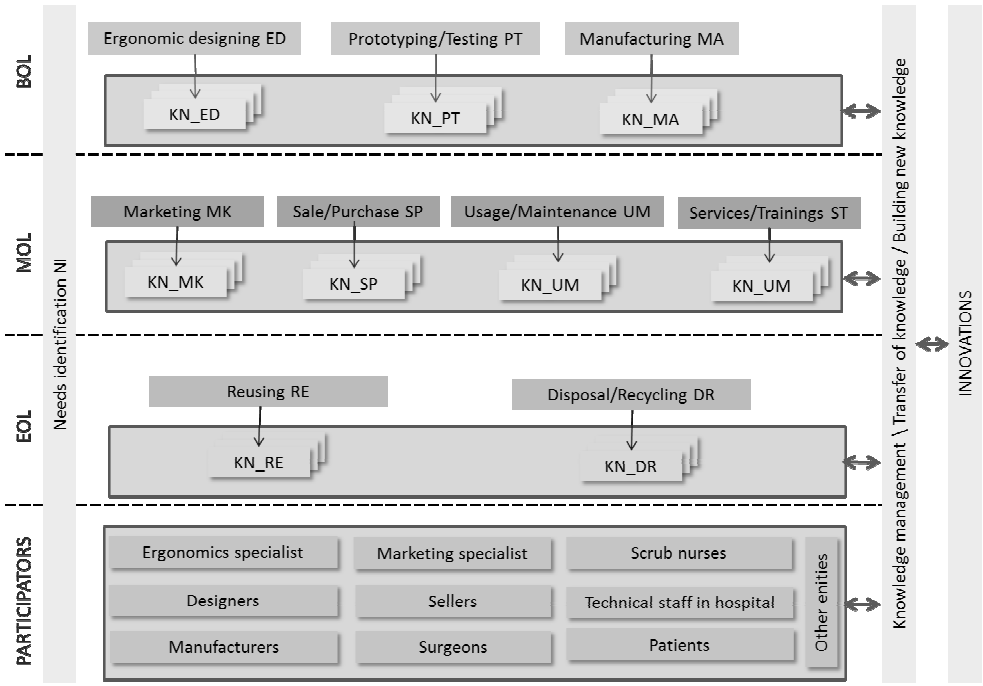

Fig. 1. Expanded diagram of the life cycle of surgical instruments

The presented diagram includes such elementary phases, which are essential to undertaking participatory approach and / or creating innovations in managing the life cycle of surgical instruments. The specific phases are following:

- BOL: Ergonomic design ED, Prototyping/Testing PT, Manufacturing MA;
- MOL: Marketing MK, Sale/Purchase SP, Usage/Maintenance UM, Services/Trainings ST
- EOL: Reusing RE, Disposal/Recycling DR.

In this context, each phase has been described in a such way that lead to the developing the mentioned above research methodology (see tab. 1.).

Apart from mentioned phases there is one special phase, which is especially important for all main stages: Needs identification NI.

Tab. 1. Description of elementary stages

Elementary stage	Description
NI	The needs resulting from the specific surgical procedures, trends, existing innovative solutions, environmental issues, etc.
ED	Designing surgical instruments taking into account human factors approach
PT	Application of rapid prototyping tools to testing and simulating the operations with using them
MA	Production of surgical instruments, including the use of virtualization techniques to computer-aided design of production technology
MK	Actions for promoting the surgical instruments at an early stage of the cycle based on virtualization technologies
SP	Purchase / sale transactions having regard to the procurement process, including preparation of SIWZ (specification provisions of crucial ordering conditions)
ST	The additional services, such as: mechanisms for sharing information about the surgical instruments; trainings based on the mechanisms of knowledge management in the area of using and servicing, which are available to medical personnel in the mobile way (available during the work processes in contextual situations) and stationary way; regeneration and investigation of their properties etc.
UM	Based on knowledge management mechanisms for supporting the processes of using surgical instruments according to intended the purpose and function as well as maintaining the usable suitability of instruments
RE	The utilization of the instruments after the withdrawal from the active use during surgical procedures to the activities of designing and testing new solutions
DR	Removal of instruments in accordance with applicable regulations and taking into account environmental aspects

The processes, which are common to all mentioned activities, are the processes of acquisition and application of appropriate knowledge resources (marked as KN_xx on the

Fig. 1) and the transfer of knowledge between the participants of the cycle. The problem for effective implementation of these processes is the diversity of both phases and tasks (within specific phase) as well as the diversity of participants in the cycle in terms of specializations, competences and geographical localization. Such an approach to the taken issues forces the targeting considerations to aspects of knowledge management, including management of explicit, tacit and implicit knowledge [31], as the basis for creating the innovation in product life cycle. This area also includes reflections on the use of appropriate and modern ICT technologies (information and communication technologies).

An approach to based on knowledge product life cycle is called as the Product Life Cycle Knowledge (PLK) in the literature. It is defined as the combination of knowledge about a product across its life time and the knowledge about all processes controlling the product life cycle or as a kind of fusion of heterogeneous knowledge about the structure, the functions, the life cycle processes, and the operational environment having impact on the product life cycle [29].

Taking into account the research area described above, it is proposed four complex tasks that are the parts of the methodology:

- 1st Task: Identification and analysis of variant models of the product life cycle.
- 2nd Task: Examination of the impact of modern information technologies IT and information - communication technologies ICT on innovation management in the life cycle product.
- 3rd Task: Development of a model for knowledge management in product life cycle.
- 4th Task: Development and verification of a model for innovation management in the LC-SI.

The performance of the indicated tasks aims at acquire a new knowledge, which will be the basis for the development of a model of innovation management in the life cycle of surgical instruments. Table 2 shows the specification of the identified tasks, together with the expected results in the form of specific knowledge resources.

Tab. 2. Description of tasks and the results in methodology of creating a model of knowledge-based innovation management in the life cycle of surgical instruments

Task	Description of task	New knowledge about:
1st Task	1.1 Identification of the number of participants in life cycle of surgical instruments LC-SI variants and analysis of their structure and the competences 1.2 Examination of the degree of the geographical dispersion of participants in the LC-SI variants 1.3 Identification and analysis of communication forms between certain participants in the LC-SI variants 1.4 Identification and analysis of the types of information resources to be exchanged between specific participants 1.5 Identification and comparative analysis of the duration of the LC-SI variants	• information gaps in the cycle, their causes and effects • communication problems (knowledge transfer), their causes and effects • bottlenecks affecting the length and course of the cycle • best and bad practices in the cycle management
2nd Task	2.1 Examination of the use of virtual technologies and ergonomic methods in an innovative approach to participatory design of surgical instruments	• a methodology for designing surgical instruments including participatory approaches,

	2.2 Examination of the usefulness of IT and ICT technologies in shaping product, operational and marketing innovations taking into account, in particular, automatic identification of data technology and rapid prototyping technology	• the determinants of innovation in the product life cycle, taking into account the different stages of the cycle, • an impact of innovative solutions in a given stage of the behaviour of the entire cycle
3rd Task	3.1 Preparing the specifications of strategic information resources in innovation management in the LC-SI 3.2 Elaboration and analysis of variant forms of notation of information adjusted to the needs of individual participants in the LC-SI 3.3 Identification and analysis of the repetitive elements of knowledge in the management of the LC-SI 3.4 Evaluation of the usefulness of modern ICT technologies in transfer of knowledge in the cycle with particular emphasis on participatory approaches in the design 3.5 Development of a formal method for notation of knowledge management model in LC-SI	• the possibilities of applying knowledge management mechanisms to improve product life cycle, • an impact of knowledge management to support the pro-innovation activities in the product life cycle
4th Task	4.1 Development of a formal methodology for notation of innovation management in the LC-SI 4.2 Elaboration of the mode of model verification 4.3 Development of guidelines for evaluating and prediction of the behaviour the product life cycle CLA in the areas: knowledge management and capacity to the pro-innovation activities	• the methodological foundations for the research and development of LC-SI in terms of innovation at different levels of complexity of the cycle • the methodologies of notation and verification of multi-dimensional model of innovation management in the LC-SI • the methodologies for conducting the product life cycle assessment and the capable for the prediction of the behaviour of cycle in terms of: knowledge management and capacity to pro-innovation activities

The whole research has been assigned to the two main stages: preliminary research, which has diagnostic nature and basic research aimed to developing and next verifying a model of innovation management in the life cycle of surgical instruments. Both stages will be supplied by carefully selected tools and research methods (Fig.2). They are located into two groups: methods of gathering the research material and Methods of analysis and elaboration of the results of preliminary the research.

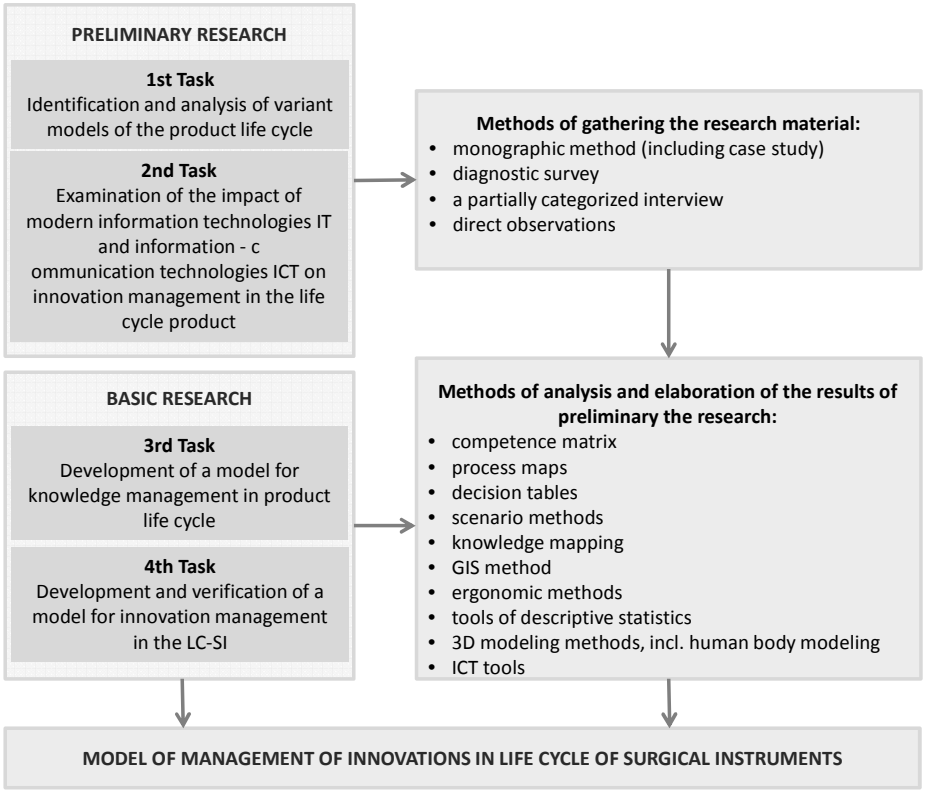

Fig. 2. The group of research methods used in the project

2. Conclusions

Management of Product Life Cycle focuses on creating, storing and retrieving data, information and, ideally, knowledge in throughout the product life cycle, starting from conceptualization to its destruction or recovery. The surgical instruments are a specific case of products, where the knowledge about them has become a crucial feature in proper treatment processes of patients. Particularly the specific needs of medical staff in area of using surgical instruments in connection with up to date ICT technologies are the impulse for creating innovations in their life cycle.

Summarising, the results of the preliminary research and the literature studies seem to confirm the lack of consistent methodological principles in managing innovations in product life cycle. The solution to this problem lies in developing a new approach to design based on participatory approach and thus creating the product innovations in the field of surgical instruments..

The methodology of studying the life cycle of surgical instruments presented in the article has a cognitive importance and the results of research will be the basis for the development of a model of innovation management within the described area.

References

1. Bartnicka J., Dąbrowski M., Mleczko K.: Application of virtualization techniques in supporting scrub nurses work. Proceedings of the IADIS International Conference e-Health, edited by Macedo M., IADIS Press, Roma Italy, 2011, 61-68.
2. Bartnicka J.: Knowledge-based improvement life cycle process of public private partnership in area of the building and exploitation of hospitals. [in:] Jacob D., Winter Ch., Winkler T. (eds.): Strategic Alliances between the Public and Private Sector, Technische Universität Bergakademie, Freiberg, 2011.
3. Bartnicka J., Bojara Sz.: Analizy ergonomiczne w wirtualnym prototypowaniu narzędzi chirurgicznych. Konferencja: Materiały na konferencję: Majówka Młodych Biomechaników 2006, Szczyrk, 12 14 maja 2006 r. Zesz. Nauk. Kated. Mech. Stosow. 2006, 30. (in Polish).
4. Martin J., Norris B., Murphy E., Crowe J.: Medical device development: The challenge for ergonomics. Applied Ergonomics, 39, 2008, 271–283.
5. Buckle, P., Clarkson, P.J., Coleman, R., Ward, J., Anderson, J., Patient safety, systems design and ergonomics. Applied Ergonomics, 37, 2006, 491–500.
6. AAMI HE74, 2001. Human Factors Design Process for Medical Devices; ISO 13407, 1999.
7. Human-Centred Design Processes for Interactive Systems; ISO 14971, 2000.
8. IEC 60601-1, 2004. General Requirements for Safety of Electrical Medical Equipment.
9. IEC 60601-1-6, 2004. General Requirements for Safety of Electrical Medical Equipment Collateral Standard: Usability, 2004.
10. IEC 60601-1-8, 2006. Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems, 2006.
11. Xie S., Tu Y.: Rapid One-of-a-kind Product Development: Strategies, Algorithms and Tools. Springer, 2011.
12. Colombo G., Filippi S., Rizzi C., Rotini F.: A new design paradigm for the development of custom-fit soft sockets for lower limb prosthese. Computers in Industry, 61, 2010, 513-523.
13. Cioccaa L., De Crescenziob F., Fantinib M., Scotti R.: CAD/CAM and rapid prototyped scaffold construction for bone regenerative medicine and surgical transfer of virtual planning: A pilot study. Computerized Medical Imaging and Graphics, 33, 2009, 58–62.
14. Niemann J., Westkämper E.: Product Life Cycle Management in the Digital Age. [in:] Intelligent Knowledge-Based Systems,Vol. II., 2005, 677-707.
15. Corso M., Martini A., Pellegrini L., Paolucci E.: Knowledge management systems in continuous product innovation. [in:] Intelligent Knowledge-Based Systems, Vol. I, 2005, 36-66.
16. Hong P., Doll W., Revilla E., Nahmd A.: Knowledge sharing and strategic fit in integrated product development projects: An empirical study. International Journal of Production Economics 132, 2011, 186-196.
17. Nonaka, I. & Nishiguchi, T.: Knowledge Emergence. Oxford: Oxford University Press, 2001.
18. Badin J., Monticolo D., Chamoret D., Gomes S.: Using the knowledge configuration model to manage knowledge in configuration for upstream phases of the design process. International Journal on Interactive Design and Manufacturing, 5, 3, 2011,

171-185, 2011.
19. Elgh F., Cederfeldt M.: Documentation and Management of Product Knowledge in a System for Automated Variant Design. – A Case Study. [in:] Pokojski J., Fukuda S. and Salwiński J. (eds.): New World Situation: New Directions in Concurrent Engineering, Part 4, 2010, 237 – 245.
20. Elgh F.: Supporting Management and Analysis of Quotations in a Design Automation Approach to Customization. [in:] Pokojski J., Fukuda S. and Salwiński J. (Eeds.): New World Situation: New Directions in Concurrent Engineering, Part 6, 2010, 401 – 409.
21. Entrup Ch., Barth T., Schäfer W.: Towards a Process Model for Identifying Knowledge-Related Structures in Product Data. [in:] Reimer U., Karagiannis D. (eds.): Practical Aspects of Knowledge Management, 2006, 189 – 200.
22. Coble, J.M., Karat, J., Kahn, M.G.: Maintaining a focus on user requirements throughout the development of clinical workstation software, in: Proceedings of the 1997 Conference on Human Factors in Computing Systems, CHI, March 1997, 22–27.
23. Garmer, K., Ylven, J., Karlsson, I.C.M.: User participation in requirements elicitation comparing focus group interviews and usability tests for eliciting usability requirements for medical equipment: a case study. International Journal of Industrial Ergonomics, 33, 2004, 85–98.
24. The Challenge of Customization: Bringing Operations and Marketing Together, http://www.strategy-business.com/media/file/sb_kw_06-16-04.pdf.
25. Broberg O., Andersen V., Seim R.: Participatory ergonomics in design processes: The role of boundary objects. Applied Ergonomics, 42, 2011, 464-472. Broberg O., Andersen V., Seim R.: Participatory ergonomics in design processes: The role of boundary objects, in: Applied Ergonomics, 42 pp. 464-472, 2011
26. Shen L., Li M., Zhao W., Zhou Z., Li Y., Wu M., Zheng J.: Web Based Cooperative Virtual Product Design Environment Shared by Designers and Customers. [in:] Shen W. et al. (eds.): CSCWD 2005, LNCS 3865, 2006, 384 – 393.
27. Batavia, A.I., Hammer, G.S.: Toward the development of consumer-based criteria for the evaluation of assistive devices. Journal of Rehabilitation Research and Development, 27, 4, 1990, 425-436.
28. Wu X., Thomson G., Tang B.: An investigation into the impact of safety features on the ergonomics of surgical scalpels. Applied Ergonomics, 40, 2009, 424–432.
29. Editorial: Frameworks and technologies for exchanging and sharing product life cycle knowledge. Computer – Aided Design 43, 2011, 459-463.
30. Lee B.-E., Suh S.-H.: An architecture for ubiquitous product life cycle support system and its extension to machine tools with product data model. International Journal of Advanced Manufacturing Technology, 42, 2009, 606–620.
31. Nonaka, I., Nishiguchi, T.: Knowledge Emergence. Oxford: Oxford University Press, 2001.

Ph.D., Eng. Joanna BARTNICKA
Institute of Engineering of Production
Silesian University of Technology
Faculty of Organization and Management
41-800, Zabrze, Roosevelta 26-28 Street
phone/fax: +48 (32) 277 73 11/ +48 (32) 277 73 62
e-mail: Joanna.Bartnicka@polsl.pl