



Reprocessing Complex Medical Devices – The Way of the Future

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Presentation by Robert Schrödel

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The Pioneer Group

- Pioneer Medical Devices AG specializes in the development, manufacturing and reprocessing of innovative and complex medical devices of limited reprocessability.
- We are the first corporation worldwide which has been granted certification as manufacturer of medical devices pursuant to the European MDD 93/42/EEG and for reprocessing of complex medical devices made by other manufacturers (so-called single-use devices) according to DIN ISO 13485.
- Our management and staff, who established the industrial reprocessing of complex medical devices in Europe over 15 years ago, use their know-how to enforce progress in technology and innovation.



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2



Pioneer Business Portfolio

Business Unit I

Classic reprocessing services & development of highly complex medical devices of limited reprocessability

- Reprocessing of highly complex medical devices made by third-party manufacturers for:
 - Cardiology / Electrophysiology
 - Orthopedics
 - Minimally Invasive Surgery (MIS)

- Total Quality Reprocessing for all-inclusive customer service

1

- Complex medical devices made by Pioneer and distributed within a „pay-per-use-system“ (CE-integrated reprocessability) for:

- Cardiology / Electrophysiology
- Orthopedics

- Full range of surgical instruments by RUDOLF Medical

2

Business Unit II

Integrated management systems and holistic services for sterile goods and medical devices

- System procurement and regulatory solutions for medical instruments, incl. instrument tray analysis and optimization, pay-per-use-solutions from a holistic point of view

3

- Financial services as the foundation for system partnerships for optimizing clinical supply and workflow processes

- Individualized Software Solutions
- Multi-Resource Planning
- Establishment of Medical Centers of Excellence
- Public Private Partnerships (PPP)

4

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3



Fit for the future

Medizinischen Fortschritt vorantreiben durch effektive Nutzung von Ressourcen



Objectives of the Strategic Partnership with Rudolf Medical

- In the center of Pioneer's involvement lies the continuous enhancement of the product and service range, always focusing on **improved efficiency** while sustaining **consistently high quality**.
- In combining RUDOLF MEDICAL's worldwide procurement network with Pioneer's Research and Development Competence, we strive for **innovative leadership** of our products and services.
- Development of a **new medical device class** – the Pioneer class of medical devices of limited reprocessability

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4



Guaranteed, Quality Ensured Supply Management

Pay-per-Use-Supply

- Hospitals and medical facilities frequently complain about **incomplete medical instrument trays** or even inadequate numbers of trays.

Pioneer's solution:

Reliable Supply Management System by using an automated tracking system, supplementing faulty trays, and providing missing instrument trays within a **pay-per-use-concept**. As a result, the hospital will not incur any **initial costs**.

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5



Guaranteed, Quality Ensured Supply Management

Strategic Procurement for High-end Medical Devices and Instruments

- Provision of contract secured medical devices and surgical instruments over a longer period of time, e.g. 5 years, based on a **quality and price level** pre-defined by the hospital.

Consequence:

The administrative and bureaucratic effort for the hospital will be reduced, and at the same time it will experience a new planning security (risk shifting).



Combining **manufacturer's know-how** (Pioneer) and **strategic decision-making authority** (hospital).

6



The Pioneer Group Worldwide



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7



Demand for breakthrough technologies!

- Population growth, medical advances and the population's increased knowledge regarding health and what is possible in medicine will inevitably lead to exploding costs if no fundamentally new treatment and management concepts can be found.
- A larger part of disposable incomes will be spent in healthcare related products and services.



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8



Why is it essential that solutions for the healthcare sector focus on efficiency?

- In Germany:
 - EUR 310 billion p.a. are spent on in-patient treatment
 - EUR 110 billion p.a. are invested in in-patient treatment
- Significant contributions can be made by:
 - **Avoiding the single-use philosophy for complex medical devices**
 - Dissolving non-transparent structures and facilitating co-action between various medical concepts
 - Optimizing clinical processes using new technologies and a coordinated process and resource management system



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9



Federal Ministry
of Health



Reprocessing medical devices in Europe

- Germany currently allows the widest scope for reprocessing of medical devices and regulates the procedure nationally through guidelines and standards.



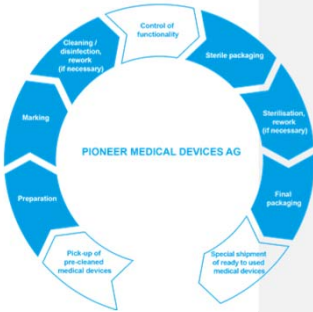
The Federal Ministry of Health does not regard the expression “for single use only” as part of the device’s intended purpose. The reprocessed device is not regarded as a remarketing of the device. Liability in this case passes to the operator.

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10



Reprocessing by Pioneer Medical Devices



- Reprocessing of medical devices by Pioneer is compliant with all applicable guidelines and quality assured by use of novel technologies, e.g. functional testing or contamination resistant coating technology.
- Based on the concept of “Total Quality Reprocessing” Pioneer offers full customer service and absolute transparency in the business process.
- Pioneer has a certified Quality Management System according EN ISO 13485 allowing the reprocessing of “Critical C” medical devices according to RKI/BfArM- recommendations



Reprocessing by Pioneer Medical Devices

- Each of our innovative solutions is designed to meet highest quality and hygiene standards, to promote medical progress and to be exclusively achieved by cost savings. We therefore refer to **sustainable value added solutions**.

The future lies in the development of ultra-complex medical devices with integrated reprocessability.





Reprocessing complex medical devices made by third party manufacturers

Making you fit for the future.

Medical progress through effective use of resources



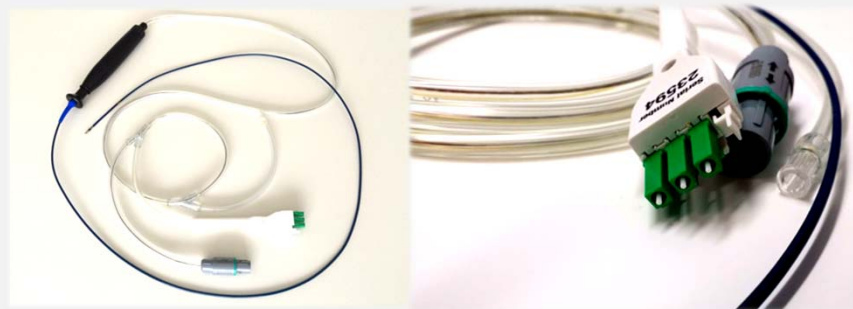
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13



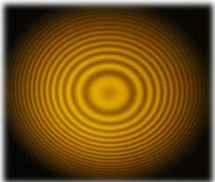
Sophisticated, new complex medical devices are constantly entering the market

Example: TactiCath



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14



Fabry-Pérot interferometer:
Interference fringes of the
Fraunhofer D line

Sophisticated, new complex medical devices are constantly entering the market

- These medical devices for electrophysiological procedures are characterized by a very sensitive and differentiated touch sensor for measuring the contact pressure during ablation.
- The sensor is used to avoid application errors and for improving performance as a whole during clinical procedures.
- These products for electrophysiological procedures are of premium quality and very expensive, the work going into the development of reprocessing procedures accordingly extensive.



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15



Reprocessing so-called chipped catheters Example: CARTO[®] 3 System by Biosense Webster

- As opposed to our competitors, by using a special reading-out generator Pioneer ensures full compliance with the Medical Devices Act, Medical Devices Operator Regulation and KRINKO / BfArM recommendation for treatment of critical "C" products.



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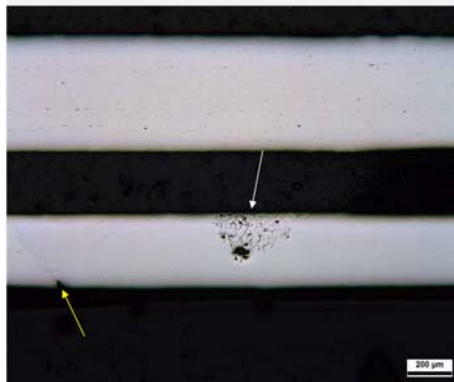
16



Defective products even during initial market introduction of low-priced orthopedic shaver systems by a major US manufacturer



Increasing Trend: poor material quality in cheap product series of medical devices



- Sample of shavers unetched, irregular weld in inner tube (yellow arrow), intergranular corrosion (white arrow) on the inner tube

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17



Increasing Trend: poor material quality in „cheap series“ of medical devices

Against the trend of producing poorer quality at a cheaper price, Pioneer offers a range of innovative products and services – because **„cheap“ simply doesn't work in healthcare.**



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18



Redesign with higher quality materials

- e.g. ground cutters and cutter heads of an orthopedic shaver system.



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19



MasterCut I.S.S. Shaver Blades

- Quality product in the field of arthroscopy
- 6-time reprocessability
- New power unit ensures compatibility with the shaver blades
- System solution with power unit within pay-per-use concept



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20



Robot-assisted Surgeries („da Vinci“-System)



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21



Critical areas of a gripping instrument for minimally invasive surgery

- e.g. tube gets squeezed in certain positions by cable mechanism.



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22



Critical areas of a gripping instrument for minimally invasive surgery

- e.g. not cleanable area in shaft interior.



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23



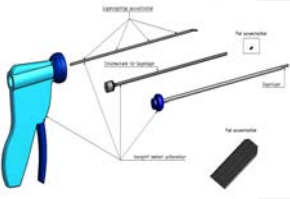
Development of a modified 3.5 LAP Instrument

- Modification of the 3.5 LAP Instrument
(Voltage test 2kVp required (currently: 1.0 kVp))



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24



Enhanced Quality and Efficiency A new dimension in the development of medical devices



- Creation of a new product category (medical devices with limited reusability)
 - a class of its own between single-use and multiple-use
 - functional and quality testing integrated within reprocessing cycle

Sustainable solutions inevitably improve the price-performance ratio.

€ cost-savings \geq 35%



Nanoparticle coatings for Complex Medical Devices

- Pioneer Medical Devices AG has the [individual rights of use worldwide](#) for applying nanoparticle coatings on complex medical devices.





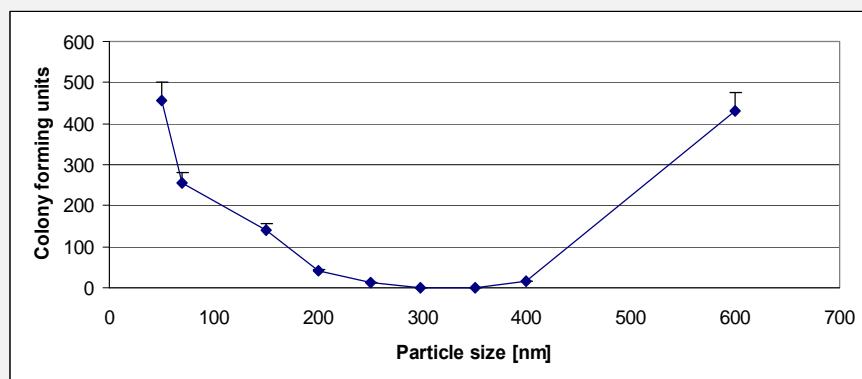
Advanced reprocessing through renewable, hygienically active nanoparticles

- During each reprocessing cycle a new nanoparticle coating is generated
 - ultra high quality of each reprocessed medical device
- Nanoparticle coating is hygienically active as it avoids adherence
 - reduction of germ concentration
- Nanoparticle coating leading to a nano-structuring of the surface
 - reduction of germ adhesion (concentration of microorganism)



Colonization of MRSA depending on particle size on the nanostructured surface

- Optimum at 300nm to 350nm





The beginning of the future opening of Europe's largest production and reprocessing centre for medical devices

- On December 09, 2013 Europe's largest and most modern production and reprocessing centre for medical devices was opened.
- Reprocessing at the highest level in terms of quality and innovation in Aschersleben (federal state of Saxony-Anhalt in the central eastern part of Germany)



29



Manufacturing and Reprocessing Plant for Medical Devices in Saxony-Anhalt



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30



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