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Review Article

Processing single-use medical devices for use in surgery – importance, status quo and potential

Aufbereitung von zum Einmalgebrauch deklarierten Medizinprodukten zum Einsatz in der Chirurgie – Bedeutung, Status quo und Potential

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Abstract

In summary, it is possible with the technology and scientific knowledge currently available to allow products intended for single use to be reprocessed using validated and certified processing procedures, while maintaining the full function and without any loss in quality. How many times a product can be re-processed must be determined separately for each individual medical technology device; it is not possible to make any kind of blanket statement as to the permissible number of cycles. This is due to the differing construction, the various combinations of materials and the diverse demands made of each device during clinical use. The exigency of the reprocessing issue is evident both to the user and the primary manufacturer. For the user, where there is a correspondingly high-quality primary product with suitably costed, technically-sound and certified reprocessing procedures, repeat usage can mean real savings while maintaining full functionality in each use. For the primary manufacturers of highly specialised instruments, only part of which can be represented by the medical facility in terms of a corresponding DRG (Diagnosis-Related Group), it is reprocessing that opens the door to widespread routine clinical use. The patient, in turn, benefits greatly from this, since his demand for medical treatment using the most up-to-date technology is taken into account.

If processing complies in full with medical technology and hygiene directives, from the medical point of view (without being able to definitively evaluate each individual case using this criterion) the specific advantages of the reprocessing procedure are obvious. In order to establish broad acceptance for the purposes of good marketing, corresponding controlling and quality instruments have to be developed to allow the decision-making process regarding the permissibility of the reprocessing of a certain device and the number of times it can be reprocessed using this procedure to be made transparent.

Taking this a step further, possibilities arise for the establishment of corresponding quality-assurance instruments on the part of the clinical establishments involved, within which reprocessed products, in the interest of quality assurance, can be referred back to the processor in the event of defective function and can also be removed from clinical use prior to completing the intended number of processing cycles. Furthermore, it can be assumed that the widespread use of reprocessing procedures in today's high-cost single-use medical device sector will have a long-term cost/price-regulating effect for the primary products, to the benefit of the users.

Thus, the heated debate regarding the safety of processing procedures that have already been certified and validated in accordance with current industry standards should be evaluated in particular from the point of view of the justified fears of the leading manufacturers with regard to their currently established market share.

From a purely surgical point of view, the reprocessing of disposable products should be welcomed as a revolution. The main criteria for surgeons and medics should always be the benefit for the patient. If

the quality is ensured through corresponding processing and validation procedures based on recognised certificates, then economic arguments take precedence.
Cases in which a DRG (and thus a payment calculation) does not fully cover the use of medical devices are conceivable. Withholding medically necessary services on grounds of the costs, or making these services available to a limited extent only, is not acceptable from the medical point of view and furthermore goes beyond what is ethically acceptable. Each procedure, even the systematic use of reprocessing of suitable medical technology disposable items, should, where the quality is guaranteed, be supported unequivocally. Taken a step further, this branch of the economy will have a long-lasting price-regulating effect on the primary producers market.

Keywords: reprocessing, economics, medical device, quality standard, surgery

Zusammenfassung

Zusammenfassend ist es zum aktuellen Stand der Technik und der Wissenschaft möglich, Medizinprodukte, die in ihrer Intention für den Einweggebrauch erzeugt wurden, unter validierten und zertifizierten Verfahren der Aufbereitung in vollumfänglichen Funktionszustand und ohne Qualitätsverlust wieder aufzubereiten.
Hierbei ist die Anzahl der möglichen Wiederaufbereitungszyklen den jeweiligen technischen Gegebenheiten des einzelnen Produktes anzupassen; es ist nicht möglich in diesem Zusammenhang eine pauschale Aussage über die mögliche Anzahl dieser Zyklen zu treffen. Dies ist bedingt durch die Verschiedenartigkeit der Konstruktionen, die mannigfaltige Kombination an Materialien und die verschiedenartigen Anforderungen an die Produkte im klinischen Alltag.
Das Themenfeld der Wiederaufbereitung ist von eindringlichem Interesse für den Anwender, wie auch für den Primärhersteller. Für den Anwender bedeutet ein qualitativ zum Primärprodukt gleichwertiges Gerät mit angemessenen Kosten, technisch einwandfrei und mit einer zertifizierten Aufbereitung, in jeder weiteren Anwendung eine reale Kosteneinsparung bei vollumfänglichem Funktionserhalt.
Für den Primärhersteller dieses hoch spezialisierten Medizinproduktes, dessen Anwendung sich zum Teil nur unvollständig in der entsprechenden DRG abbilden lässt, kann dies zudem bedeuten, dass mit Hilfe der Wiederaufbereitung unter Rentabilitätskriterien erst der Eingang in die breite Anwendung im klinischen Alltag realisiert werden kann.
Der Patient im Gegenzug profitiert in herausragender Weise, zumal seinem Anspruch, in der Behandlung die aktuellste Technologie zu erhalten, erst so Rechnung getragen werden kann.
Wenn die Technik der Aufbereitung den Anforderungen der Medizintechnik und den Vorgaben der Hygiene vollständig entspricht, dann sind aus medizinischer Sicht (ohne dass man im Stande sein wird jeden Einzelfall entsprechend dieser Kriterien zu prüfen) die Vorteile der Wiederaufbereitung offenkundig. In der Bemühung ein Bewusstsein bei den Entscheidungsträgern zu erreichen mit der Intention einer vernünftigen Markteinführung, müssen vergleichende Kontroll- und Qualitätsinstrumente erstellt werden, um die Zulassung der Aufbereitung eines speziellen Instrumentes und die Festlegung der Anzahl der maximal zu durchlaufenden Zyklen zu ermöglichen.
Hieraus können sich zukünftig Impulse für die etablierten Qualitätskontrollmechanismen ableiten lassen, so dass im Interesse der Qualitätssicherung, defekte Geräte in den Aufbereitungsprozess wieder eingegliedert oder gar vor Erreichen der geplanten Rezirkulationszyklen vorzeitig als defekt ausgeschleust werden können. Darüber hinaus ist davon

auszugehen, dass der flächendeckende Einsatz der Wiederaufbereitung in dem heutigen kostenintensiven Einweg-Medizinprodukte-Geschäft einen langfristigen Preis-regulierenden Effekt zum Nutzen der Anwender auf das Preisniveau der primären Medizinprodukte haben wird.
Demzufolge muss die aktuell engagiert geführte Debatte, um die Sicherheit wieder aufbereiteter Medizinprodukte, die bereits nach zertifizierten und validierten Verfahren unter Berücksichtigung der geltenden Industrierichtlinien aufbereitet werden, unter dem Blickwinkel der Primärhersteller und deren Sorge um die etablierten Märkte neu bewertet werden.
Aus rein chirurgischer Sicht sollte die Möglichkeit der Anwendung wieder aufbereiteter Produkte als Revolution willkommen geheißen werden. Das Hauptargument für Chirurgen und andere Ärzte kann nur der Vorteil für ihre Patienten sein. Sobald die Qualität auf der Grundlage anerkannter Zertifikate durch vergleichbare Prozesse und validierte Abläufe abgesichert ist, steht das Argument der Wirtschaftlichkeit in vorderster Reihe.
Medizinische Anwendungen, bei denen die hinterlegte DRG den Sachkostenanteil des Medizinproduktes nicht vollständig abdeckt, sind vorstellbar. Das Zurückhalten spezialisierter medizinischer Leistungen aus Kostengründen, bzw. die Zugänglichkeit dieser Leistungen lediglich für ein ausgewähltes Klientel, ist aus ärztlicher Sicht untragbar und verstößt gegen anerkannte ethische Grundsätze.
Jede Technologie, wie beispielsweise das Verfahren der Wiederaufbereitung geeigneter Einweg Medizinprodukte, sollte bei gegebener Qualitätsgarantie uneingeschränkt unterstützt werden. Zukünftig wird diese Seite der Ökonomie einen nachhaltig Preis-regulierenden Effekt auf den Markt der primären Einweg-Medizinprodukte haben.

Schlüsselwörter: Wiederaufbereitung, Ökonomie, Medizinprodukt, Qualität, Chirurgie

Introduction

The purpose of this discussion is to describe and assess the current status, importance, potential and possible risk involved in the re-processing of medical devices designed for single use.
The re-processing of single-use products is the subject of some controversy in medical circles. This is due to the various interests associated with each individual product. First and foremost, a distinction must be made between the manufacturer's interests and the interests of the user. Manufacturers are businesspeople with financial goals. As such, they strive to secure themselves an exclusive position using high-quality products in strategically restricted markets, leading to a lasting association between the quality of the product and the manufacturer's name. Users within medical circles, on the other hand, are subject to high-quality demands in terms of product characteristics and intra-operative care. The sensitive area of the use of single-use products in surgery affects many products that use staples and staple-stitch seams, as well as devices used in interventionist diagnostics and therapy. In the daily competition between surgical clinics, single-use products account for a significant proportion of operative equipment. However, in view of the compulsory increasing use of projected budgets that conform with SOPs (standard operative procedures) in operative wards, they simultaneously represent an increasing cost factor. In addition to manufacturer and user interests, a third variable in this discussion is the sterilised goods industry, a young and promising branch, which has been increasingly visionary over the last few years in its commitment not only to the reprocessing of multi-use products but also to the reprocessing of single-use-products in the highly-specialised medical devices market.
As is so often the case with fundamental innovations and the introduction of revolutionary technology – above all in medicine – there are currently more sceptics and critics than proponents. In the interests of maintaining a healthy degree of scepticism, the task now is to find the balance between the maintenance of high standards and improving patient safety while observing established industry standards on the one hand; and on the other, sustaining the necessary degree of liberalism paired with a long-term visionary view regarding new technologies.
One example of this is the decision to allow individual products to be reprocessed, whereby reprocessing is limited to a low number of re-sterilisation cycles only. In this way, while maintaining the product-specific quality levels when carrying out sensitive reprocessing procedures tailored to demand, widespread clinical use is ultimately facilitated through the recurring availability. One example of this is the introduction of reprocessing algorithms for paediatric cardiological interventionist diag-

nostic catheters, which, despite excellent diagnostic properties, were not able to become established on the market as a result of above-average costs. This was until re-use through horizontal financing of the use of this diagnostic technique facilitated by resterilisation procedures allowed the cost-effectiveness threshold to be attained.

When dealing in theoretical terms with the reprocessing of medical devices declared as being single-use only, in addition to the basic requirements such as hygiene and technical suitability, liability issues must also be taken into account. The prerequisite for the widespread introduction of this new product group is compliance with the quality standards as defined in national and international directives. This encompasses the requirement that the processing of these articles must be carried out by suitably certified sterilised goods processors using specially validated procedures. In terms of liability law, these procedures must be assured by the processing company to exactly the same extent, analogous to the status of the primary manufacturer. In this connection, a specific feature that has to be taken into account is that, after reprocessing, the medical device must have the same qualitative status as a new product in terms of liability law, above all for the patients. This, in turn, can only be ensured if the processing company can prove that it has a corresponding certificate issued by an accredited body.

The reprocessing company must at this point be told how many reprocessing cycles may be carried out per product. Suitable, clear, unalterable, preferably software-/hardware-based identification procedures must also be observed in the course of the reprocessing.

Requirements for various groups of products

The indispensable precondition for the reprocessing of a product is the suitability of the material characteristics. On the product side, it must be possible to fulfil the technical requirements on which the reprocessing is based. In addition to thermal stability during the sterilisation cycle, it must be possible to re-clean the product repeatedly. In the case of complex components, which involve the replacement of mechanisms and/or material, it must be possible to temporarily dismantle the device while maintaining full function. Particular challenges arise in the case of the replacement of materials within a product group.

The requirements resulting from the different product groups vary greatly and are defined primarily in terms of their technical construction. In addition to the replacement of materials, as mentioned above, identical quality criteria apply to the processing of both compact devices and those made up of several individual pieces or tubular constructs. Firstly, all geometric specifications, as well as the various raw materials used within the medical devices (e.g. plastics, metal, thermo- and duroplasts, etc.), but in particular a range of functional elements, (as found in the form of plug-and-socket and clamp connections or operating switches), which are fixed or can be dismantled, must be able to withstand the demands of reprocessing. Secondly, it must be possible to process and reconstruct these devices just as effectively while retaining function. Product groups from the single-use products sector, which, from a medical/medical-surgical point of view can be reprocessed, include tubing systems for surgical field supply and waste removal, devices from the staple stitching segment (linear cutters, circular staplers) and from interventionist diagnostics. Catheter therapy systems, high-quality chip and monitoring systems as components in surgical-feed products, as well as handles and sockets for operating instruments from the high-frequency field (radio frequency–ablation probes and ultrasound equipment) are among the products for which repeated use would be desirable from both the surgical and the financial point of view, provided function is not affected and the products pass through a validated processing procedure.

The range of contra-indications must be expanded accordingly due to quality-defining factors; this task is just as painstaking as determining the permissibility of the reprocessing of disposable products. However, an across-the-board rejection of reprocessing is by no means the predominant reaction here; the quality of the product and ensuring patient safety must be at the forefront of discussions. At this point it should also be emphasised that, while the indication should be narrow, where conformity with the intended quality criteria is proven, the criteria for allowing products to be reprocessed should be broadly-defined and encouraged.

Disputes are currently ongoing between the processors and the primary manufacturers in the subject area of reprocessing single-use-products. The focus is on the conflicting economic interests. In the interests of the patients, the sole criterion should be the quality of the product. In the interests of the German welfare state, which is anchored through the health insurance companies within the framework of the social security legislation and within a common insurance community (as exists in the healthcare system and as defined by statutory health insurance schemes) costs-saving potential must be clearly demonstrated, defined and used accordingly, particularly in view of the current financial situation in the healthcare system. The use of validly processed single-use products has resulted, for example, in high-quality (and thus expensive) medical technology products, which were not previously able to become established on the market due to their prohibitively-high purchasing costs, being able to gain a fixed place in diagnostics and therapy as a result of and through the possibility of repeat usage.

With the introduction of a diagnosis-based payment system in Germany, pursuant to which medical services are categorised in a pre-defined payment system according to grouping and allocation of a corresponding case value, hospital operators are being forced, for purely economic reasons, to close the gaping void between the maximum spectrum of diagnostics and the corresponding therapies

to the lowest possible costs in order to maintain their clinic structures.

In this field, processing procedures for high-value single-use technical products represent a significant factor in the optimisation of the financial situation of medical establishments.

When it comes to consideration of the marginal areas of this issue, where the determination of indication/authorisation and contraindications/exclusion of medical single-use products from reprocessing is concerned, it quickly becomes clear where the hidden risks of reprocessing lie. In addition to the validation and supervision demanded by the reprocessing quality standards, corresponding rules for ongoing quality control must be agreed in advance for each product/product group. Here, the technical construction, the material composition and the complexity of the construction of the individual instruments define the number of reprocessing cycles that are technically possible. Clear instructions and control mechanisms must be defined, so that the reprocessed products can be withdrawn from the reprocessing cycle at an agreed point in time in the event of any deterioration in quality. If rules for qualitative exclusion have been agreed, it is, in principle, conceivable for every medical/medical technology product that is technically qualified for processing to be subjected to a corresponding advance validation procedure. In this context, identification and monitoring instruments/mechanisms are thinkable only as part of software-based partially/fully automated data bank systems; to date it has not been possible, not only for the disposable area, to estimate the full potential of such systems for the clinic operators within the entire logistics chain of material supplies and administration.

A point of historical interest should be mentioned here: in Germany, even before 1986, and thus before the rise of widespread public awareness of potential contamination with life-threatening infectious diseases such as Hepatitis or HIV, it was customary that, with the consent of the relevant hygiene bodies, appropriately sterilised medical goods (single-use products also) could be provided to medical facilities in the developing countries as part of medical aid projects/cooperation projects after passing through a simple, non-certified process and without involving any liability insurance requirements. This also included non blood-contaminated sections of artery-replacement and bypass prosthetics made of non-biological material, as well as opened, unused stitching material.

According to the German and English-language literature currently available via medical databanks in the European/international field on the subject of the processing of single-use medical products, no lasting side-effects have been published. Specifically, to date there have been no known cases of transfer of infectious disease through inadequate reprocessing procedures.

Benefit-Risk Balance

As part of the benefit and risk assessment, the main points of contention will be, on the one hand, the technical feasibility of reprocessing, and on the other the economic sense of reprocessing. A user and/or clinic operator will be interested (in the long term) as part of their financial framework, (which is financed by third parties) in being able to use a high-quality instrument with high-quality technology several times in return for a low-level service charge, thereby increasing the economic success rate. Equally, in the long-term the primary manufacturer will pursue economic interests, i.e. he will attempt to ensure that his single-use product is not re-used. The primary manufacturer will emphasise this position by unequivocally excluding liability for any failure to function correctly resulting from reprocessing. From today's perspective, however, this appears to be a less important problem, since the sterile goods processors already provide assurances to this effect as part of the validation of the processing procedure.

As explained above, determining the permissible number of processing cycles is currently geared to the technical feasibility of processing; statutory requirements/rules defining the point in time when a reprocessed product is deemed no longer to be fully functional are currently regulated only by the reprocessing industry itself, which must assume the corresponding liability obligations in the event of a reprocessing-related malfunction.

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