REUSABLE STERILIZATION CONTAINER SYSTEM
### Executive Summary

#### CLINICAL VALUE

<table>
<thead>
<tr>
<th>Unmet Clinical Need</th>
<th>Reusable Sterilization Containers were Designed to Address Clinical Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital-acquired infection, including infection resulting from non-sterile surgical instruments, implants, and medical devices, poses a significant risk to patients.(^1)</td>
<td>DePuy Synthes Reusable Sterilization Containers are designed to allow sterilization of the enclosed medical devices and maintain sterility for a maximum of 180 days. Based on internal validation*, there is less than a 1:1,000,000 chance that a single viable microorganism is present on a sterilized item when using the Reusable Sterilization Container System with DePuy Synthes Companies (Trauma, CMF, and Spine) instruments and/or implants. Maintaining sterility of instruments and implants helps support hospital anti-infective strategies.(^2)</td>
</tr>
<tr>
<td>Tears in blue wrap require re-sterilization, which can delay surgery and/or prolong operating room (OR) time as much as 30 minutes,(^3) leading to increased risk of postoperative morbidity and mortality.(^4-7)</td>
<td>The DePuy Synthes Reusable Sterilization Container System may eliminate the need for re-sterilization during a surgical procedure. Unexpected sterilization may delay the surgical procedure as much as 30 minutes.(^8) Re-sterilizations and longer surgical times lead to a greater risk of infection and blood loss for the patient.(^6,9) For hospitals, longer procedure times and re-sterilizations result in increased costs in addition to the risk of infection, pneumonia, extended intubation, deep vein thrombosis, and other complications.(^4-7)</td>
</tr>
<tr>
<td>Implants and instruments that are contaminated or have bioburden should be covered during transport to/from the OR.(^3) Containers with handles tend to be easier to transport, and covered containers also provide an easy way to move instruments back and forth from the OR.(^3)</td>
<td>Reusable Sterilization Containers, with handles and covers, are designed to facilitate transport within a healthcare facility. Hospital staff may transport sterile surgical instruments from the storage location to the OR in preparation for a procedure. If the Reusable Sterilization Containers are used to transport contaminated instruments following the procedure, the container may minimize exposure of hospital staff and other patients to potential contaminants during transport.(^10,11)**</td>
</tr>
</tbody>
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\(*\) Validated process demonstrating a sterility assurance level (SAL) of \(10^6\)

\(**\) Must following ANSI/AAMI ST79:2010\(^{10}\) guideline and the AST Standards of Practice for the Decontamination of Surgical Instruments\(^{11}\)
ECONOMIC VALUE

Economic Challenge

Maintaining sterile medical devices using blue wrap is resource intensive and costly.\(^3,12\)

The DePuy Synthes Reusable Sterilization Container System provides cost savings as a result of the lower occurrence rate of re-sterilization, as well as the reduction in staff time for sterilization. Over 5 years, the cumulative cost savings to a hospital from the adoption of a Reusable Sterilization Container in lieu of blue wrap for a single surgical tray is estimated to be $10,171 and $21,358 at 10 years* (Figure 1).\(^{13}\)

**FIGURE 1:** Cumulative Cost Savings with the DePuy Synthes Reusable Sterilization Container Over 10 Years are Substantial

Some facilities have reported facility-wide cost savings of more than $21,000 in the first year and over $48,000 in the second year after a facility-wide transition to reusable sterilization containers.\(^{12}\) While it may only cost a few dollars to wrap a tray with blue wrap, the cost savings of using sterilization containers add up quickly given a tray may last 10 years or more.\(^3\)

*Note: The DePuy Synthes Reusable Sterilization Container System was validated for up to 100 processing cycles.

Hospital waste disposal and recycling costs are substantial.\(^2,12,14,15\)

The DePuy Synthes Reusable Sterilization Container System provides cost-savings as a result of reduced blue wrap use/waste, while also addressing the long-term impact of surgical waste on the environment. A facility that implements a transition from blue wrap to rigid sterilization containers will not only substantially reduce the amount of waste (Figure 2) but also reduce the consumption of landfill space, oil, energy, water, and CO\(_2\) that are associated with waste disposal.\(^\)\(^{12}\)

**FIGURE 2:** Reduction in a Facility’s Total Blue Wrap Waste after Switching to Reusable Sterilization Containers

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<table>
<thead>
<tr>
<th>Year</th>
<th>Disposable Wrap Cost</th>
<th>DePuy Synthes Reusable Sterilization Container Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>$2,273</td>
<td>$1,052</td>
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*Note: The DePuy Synthes Reusable Sterilization Container System was validated for up to 100 processing cycles.*
BACKGROUND

Epidemiology

It is well-understood that hospital-acquired infection poses a significant risk to patients. In the United States alone, approximately 46.5 million surgical procedures are performed each year. Every time a medical device or surgical instrument comes into contact with a patient’s sterile tissue or mucous membrane, there is a major risk of introducing pathogens that may lead to infection. Failure to properly disinfect or sterilize equipment carries risks associated with breach of host barriers as well as risks for person-to-person transmission (e.g., hepatitis B virus) and transmission of environmental pathogens (e.g., Pseudomonas aeruginosa). According to a survey of 10 geographically diverse, acute care hospitals in the United States and data from the 2010 Nationwide Inpatient Sample, there were an estimated 722,000 healthcare-associated infections, including 157,000 pneumonia cases, 157,500 cases of surgical site infection from inpatient surgery, and 71,900 primary bloodstream infections. The Centers for Disease Control and Prevention estimated that 75,000 hospital patients with healthcare-associated infections died during their hospital stay in the same year. Addressing the variety of risks of infection is critical for each of the millions of procedures performed annually.

Clinical Burden

For patients requiring surgical procedures, surgical instruments, implants, and medical devices are one way that healthcare-associated infections can be transmitted. Medical equipment can be categorized based on its risk of spreading infection, and these categories aid decisions about whether to decontaminate or dispose of a used medical device. Decontamination is the process by which a reusable device is rendered safe for further use through cleaning and either disinfection or sterilization. It is a process which usually involves extensive quality control. Most microorganisms are inactivated or destroyed by disinfection but sterilization is required to eliminate resistant organisms and bacterial spores. Steam sterilization is an essential part of infection prevention for surgical instruments, implants, and medical devices. Historically, the primary method for sterilization included the use of blue wrap with steam sterilization; however, hospitals and OR staff have another option in the form of reusable rigid sterilization containers.

Given the risks of infection, it is imperative for OR staff to visually inspect for holes or tears in the blue wrap prior to and during a surgical procedure. Despite the skill and efficiency of processing technicians, holes in blue wrap occur frequently. In many cases, the patient may already be on the operating table and/or under anesthesia. In the event that blue wrap is torn, re-sterilization must be performed to ensure patient safety. One facility performed immediate use steam sterilization/re-sterilization in 10.2% of procedures performed in 2008. Unfortunately, the resulting delay of the surgical procedure or the extension of operative time, also poses additional risk that the patients will experience postoperative morbidity or mortality.

Even with a visual inspection of surgical instruments by trained medical personnel, research suggests that tear detection rates range from 6.7% to 96.7% for the smallest to the largest defects, respectively, meaning that the smallest tears (1.1 mm) are missed 93.3% of the time while the largest tears (10 mm) are missed 3.3% of the time. A study by Waked et al reported that defects in blue wrap with a diameter approximately that of a pencil (6.7 mm) were missed 18% of the time, although contamination can be transmitted by a nail with the diameter of a pin (1.1 mm). These results raise questions about the use of blue wrap and common visual screening for holes in the prevention of serious infection.
Economic Burden

Although blue wrap may initially seem inexpensive, the lifetime cost of blue wrap adds up quickly. Using a surgical tray as an example; if a tray costs $2 each time it is wrapped, and it is wrapped once per day for the 10-year life of the tray, the cost of the blue wrap for a single surgical tray is upwards of $7,000.\(^3\) The cost would increase further if the tray was wrapped and/or sterilized more than once per day, as in the event of a tear in the blue wrap. Not only is there a material cost for the blue wrap, there is also substantial staff time required to wrap and tape instruments.\(^3\)

In addition to the time required for sterilization using blue wrap and the cost of the blue wrap itself, it is important to consider the cost of disposal as well. Every year 4 billion pounds of waste are produced by healthcare facilities, and the amount continues to increase annually. Up to 70% of healthcare waste originates from a hospital’s operating room,\(^23\) and estimates suggest that 12% to 19% of surgical waste is from blue wrap.\(^{24,25}\) Additionally, up to 90% of operating room waste is improperly sorted and sent for costly and unneeded hazardous waste processing.\(^23\)

To tackle the cost and waste-related challenges of the ubiquitous blue wrap, it has been suggested that changes in sterilization and hospital waste management include substitution of blue wrapped surgical trays with reusable metal cases.\(^23\)
PRODUCT DESCRIPTION

DePuy Synthes Companies offers an assortment of rigid, reusable containers that allows for sterilization of the enclosed medical devices and maintains sterility of the devices until used, for a maximum of 180 days. The Reusable Sterilization Container System is designed to deliver clinical and economic value to the hospital, surgeon, and patient. The key features of the Reusable Sterilization Container System include:

• Anodized aluminum rivet-less case assembly,
• Silicone gasket secured with a stainless steel dual action latching mechanism,
• Offset perforated retention, eliminating any direct path through the lid,
• Single-use disposable filters provide 100% barrier efficacy with each and every use*,
• Availability of containers with a solid or perforated bottom, and
• Availability of a range of sizes, including extended sizes for large orthopedic sets.

Selecting a compatible container for an orthopedic instrument/implant set involves not only validation testing, but also ensuring the set is within the cleared indications of the container. The indicated lumens (quantity, diameter, and length), materials, and the volume-to-vent ratio are some of the key considerations when choosing a proper container.26

The DePuy Synthes Reusable Sterilization Container System is validated to provide effective sterilization for DePuy Synthes Companies (Trauma, CMF, and Spine) instruments and implants, reducing the ambiguity of set sterility.

*when used according to the Instructions for Use
This value analysis brief presents information on the design features and potential clinical and economic benefits of using the DePuy Synthes Reusable Sterilization Container System. The referenced data for this value brief were obtained through searches of EMBASE/Medline in OVID and PubMed on sterilization containers as well as OR time and patient outcomes published in the last 10 years. Search terms for the sterilization container search included “sterilization container”, “sterilization case”, “sterile wrap”, “blue wrap”, and “rigid container”; search terms for the OR time and patient outcomes search included “operative time”, “operative duration”, “intraoperative complications”, and “postoperative complications”.

DePuy Synthes Reusable Sterilization Containers are designed to sterilize the enclosed medical devices and maintain sterility for up to 180 days. Effective sterilization is imperative in preventing the transmission of infectious organisms and reducing the rate of hospital-acquired infections.\(^2\)

Given the significant risk that hospital-acquired infection poses to patients\(^1\) and the fact that surgical instruments, implants, and medical devices are primary modes of infection transmission,\(^19\) hospitals need a reliable method for sterilizing surgical equipment to be used in the OR.

The DePuy Synthes Reusable Sterilization Container System allows for sterilization of the enclosed medical devices and maintains sterility of the devices until used, for a maximum of 180 days. The containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used according to the instructions. The following features of the container system were designed to promote hospital anti-infective strategies related to sterilization of medical devices:

- Disposable filters allow ingress and egress of sterilant, while providing a microbial barrier.
- Tamper-evident arrows provide a visual indicator that the container has been exposed to a specific sterilization cycle parameter and has not been inadvertently opened prior to use.
- Data cards provide a record regarding specific sterilization process load.

In addition, the sterilization container system is validated to provide effective sterilization for DePuy Synthes Companies (Trauma, CMF, and Spine) instruments and implants in line with The Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities\(^27\) from the Association for the Advancement of Medical Instrumentation (AAMI). The AAMI’s validation standard for containment devices requires a manufacturer to demonstrate through validation testing that the contents of a container or other packaging can be processed to a sterility assurance level of \(10^6\) under the conditions recommended in their instructions for use.\(^27\) Based on this validation, there is less than a 1:1,000,000 chance that a single viable microorganism is present on a sterilized item when using the Reusable Sterilization Container System with DePuy Synthes Companies (Trauma, CMF, and Spine) instruments and/or implants. Maintaining sterility of instruments and implants helps support hospital anti-infective strategies.\(^2\)
Using the DePuy Synthes Reusable Sterilization Container System can eliminate the need for re-sterilization due to torn blue wrap. Tears in blue wrap may delay a surgical procedure and/or increase operative time, which results in increased costs and may have a negative effect on patient outcomes.\(^3,4\)

Unfortunately, torn blue wrap is common in the OR and requires re-sterilization to ensure patient safety. Regardless of which is performed, tears in blue wrap can delay a surgical procedure and/or substantially increase the operative time.\(^3\) The increase in operative time could require extended intubation, more anesthesia, and higher costs. In addition, research indicates an association between increasing operative time and worse patient outcomes.\(^4-7\) For example, one study followed 4,588 patients undergoing single-level lumbar fusion; longer operative time was associated with higher risk of complications, including medical complications, surgical complications, superficial surgical site infection, and postoperative transfusions.\(^4\) Operative duration of 5 hours or more was also associated with increased risk of re-operation, organ/space surgical site infection, sepsis/septic shock, wound dehiscence, and deep vein thrombosis.\(^4\) Therefore, OR time should be considered a key quality metric, and strategies aimed at reducing OR time are a key component to improve long-term patient outcomes.\(^4\)

Using the DePuy Synthes Reusable Sterilization Container System will eliminate the need for re-sterilization in the OR due to torn blue wrap. Eliminating the need to use blue wrap will help reduce OR time, limiting the risks to the patient.\(^4-7\)

The DePuy Synthes Reusable Sterilization Containers are designed to facilitate transport within a healthcare facility.

Hospital staff time is required to transfer sterile surgical equipment in preparation for surgery; staff also transfer used instruments following a procedure, which may increase risk of exposure to biohazards.\(^3\) DePuy Synthes Reusable Sterilization Containers, with handles and covers, are designed to facilitate transport within a healthcare facility. Hospital staff can easily transport sterile surgical instruments from the storage location to the OR in preparation for a procedure. If the Reusable Sterilization Containers are used to transport contaminated instruments following the procedure, the container may minimize exposure of hospital staff and other patients to potential contaminants during transport.\(^10,11\) **

**Must following ANSI/AAMI ST79:2010 guideline and the AST Standards of Practice for the Decontamination of Surgical Instruments**
ECONOMIC VALUE

The DePuy Synthes Reusable Sterilization Container System may provide opportunities for hospital cost-savings by eliminating the need for blue wrap and reducing the rate of re-sterilization.

Maintaining sterile medical devices using blue wrap is resource-intensive and costly.\textsuperscript{3,12} Despite the low materials cost to wrap an individual instrument compared to the higher up-front cost of a single reusable metal container, the DePuy Synthes Reusable Sterilization Container System is effective at providing sterile surgical instruments and also provides cost-savings for the hospital at 1, 5, and 10 years.\textsuperscript{13} The Reusable Sterilization Container System reduces the time spent by processing technicians to wrap and tape, sterilize, and visually inspect surgical equipment prior to a surgical procedure. However, cost savings are realized by reducing the need for re-sterilization due to torn blue wrap.

Specifically, the cost of wraps, tapes, labor, and wrap disposal per tray cycle is estimated at $2.44. Assuming 50 cycles per year per surgical set, the total processing cost is $122.00. However, the costs due to torn blue wrap and/or sterility expiration must also be considered. Assuming a 7% occurrence rate for torn blue wrap, a 34 minute sterilization cycle, and the OR cost of approximately $63 per hour, the incremental cost for torn blue wrap exceeds $2,150. This results in an annual estimate cost of $2,272 per surgical set. In contrast, the purchase price for the DePuy Synthes Reusable Sterilization Container is $1,017, with an additional $35 per year for the disposables (i.e., arrows, data cards, filters), for a total annual cost per container of $1,052. At year 5, the potential cost savings to the hospital from the adoption of the Reusable Sterilization Container totals $10,171; at year 10, the savings totals $21,358 (Figure 3).\textsuperscript{13}

**FIGURE 3:** Cumulative Cost Savings with the DePuy Synthes Reusable Sterilization Container Over 10 Years* are Substantial

<table>
<thead>
<tr>
<th>Year</th>
<th>Disposable Wrap - 1 surgical set</th>
<th>DePuy Synthes Reusable Sterilization Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>$2,272</td>
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*By Year 10 Reusable Sterilization Container provides cost savings in excess of $20,000, a 15-fold reduction in sterilization costs.

Facilities implementing a full transition from blue wrap to sterile rigid containers should evaluate their costs before, during, and after the transition. One facility saw facility-wide cost savings of more than $21,000 in the first year and over $48,000 in the second year.\textsuperscript{12} Use of Reusable Sterilization Container Systems in lieu of blue wrap is one of many ways hospitals can reduce costs and burden on staff.
Using the DePuy Synthes Reusable Sterilization Container System provides cost-savings as a result of reduced blue wrap waste, while also addressing the long-term impact of surgical waste on the environment.

Four billion pounds of waste are produced by healthcare facilities annually, and a significant portion of that waste is blue wrap. Unless important steps are taken, the amount of waste is expected to continually increase.\textsuperscript{23,24} The disposal costs for hospital solid waste vary depending on geography/location and disposal method from $44 to $68 per ton (approximately $0.03 per pound). Efforts to reduce the amount of blue wrap waste for disposal can produce direct cost savings. In one facility that began simply recycling—rather than disposing of—used blue wrap saw a cost-savings of $544 in one year.\textsuperscript{24} Although blue wrap can be recycled, evidence suggests that recycling may not be available or convenient for many healthcare facilities.\textsuperscript{3} Considering that recycling of blue wrap has a cost of its own, hospitals and other facilities that adopt the DePuy Synthes Reusable Sterilization Container System could expect cost savings from substantially reducing the amount of blue wrap all together.

In addition to the potential for cost savings, the use of the Reusable Sterilization Container System helps address the long-term impact of surgical waste on the environment. One facility that implemented a transition from blue wrap to sterile rigid containers quantified their total blue wrap waste before, during, and after the transition; the facility reported a reduction of over 7,000 pounds of wrap in the first year and nearly 12,000 pounds in the second year after the transition (Figure 4).\textsuperscript{12}

\textbf{FIGURE 4: Reduction in a Facility's Total Blue Wrap Waste after Switching to Reusable Sterilization Containers}

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{chart1.png}
\caption{Transition from disposable blue wrap to Reusable Sterilization Containers results in substantially less waste. Facility-wide waste was reduced 7,424 pounds in \textit{Year 1} and nearly 12,000 pounds in \textit{Year 2}.}
\end{figure}

The same facility's efforts saved over 340 cubic yards of landfill space, over 7,800 gallons of oil, and over 65,000 kilowatts of energy, among other environmental savings.\textsuperscript{12} In addition to reduced disposal and/or recycling costs, the DePuy Synthes Reusable Sterilization Container System can facilitate the movement toward more environmentally conscious healthcare delivery, beginning in the OR.
CONCLUSION

The DePuy Synthes Reusable Sterilization Container System provides a solution for a healthcare facility’s sterilization needs while minimizing the impact on budget as well as the environment. By eliminating the need for blue wrap, the Reusable Sterilization Container System reduces the need for re-sterilization during a procedure. Eliminating the need for blue wrap may also have an impact on reducing the infection rate, staff time required for sterilization (e.g., wrapping and taping instruments with blue wrap), and total OR time.\textsuperscript{3,21} Additionally, the Reusable Sterilization Container System is validated to provide effective sterilization for DePuy Synthes Companies (Trauma, CMF, and Spine) instruments and implants, therefore eliminating the need for the hospital to conduct any further validation. Use of the Reusable Sterilization Container System provides a return on investment by reducing costs while also minimizing waste and environmental impact. The Reusable Sterilization Container System was developed to deliver clinical and economic value to healthcare facilities, OR staff, and patients.
REFERENCES


13. DePuy Synthes Sterile Containers ROI vs Blue Wrap. DSUS/TRM/0315/0545


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