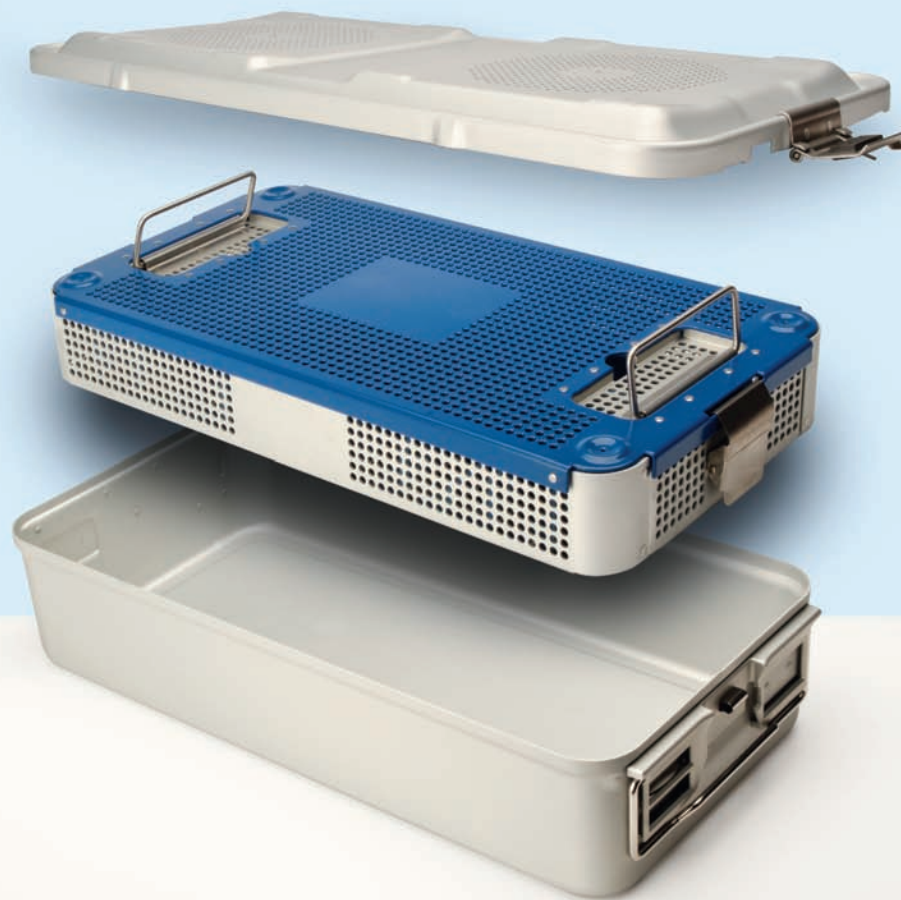


SterilContainer™ Systems

Business to business sales model



Aesculap Surgical Technologies- Sterile Processing

AESCLAP®

Company overview



Advances in health care are made from a willingness to face change with innovative solutions which shape the future of medicine. This means taking responsibility for recognizing opportunities in the marketplace and identifying the customer's needs.

As the world's largest surgical instrument manufacturer, Aesculap designs and produces surgical instruments, sterile containers, implants, wound closure products and motors for several surgical specialties including: ENT, plastic and reconstructive, thoracic, cardiovascular, orthopedic, gynecologic and general surgery as well as neurosurgery and minimally-invasive surgery.

The company was founded in 1867 by master craftsman Gottfried Jetter in Tuttlingen, Germany. For more than 140 years, the name Aesculap has been synonymous with quality throughout the world. Today, modern technology blends with Aesculap Old World tradition to provide healthcare professionals with the widest array of surgical products available from a single manufacturer.

Aesculap, a B. Braun company, stands for the continual exchange of knowledge and experience in medicine. We are an independent family-owned business that embraces the opportunities presented by the global marketplace.

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Meeting the needs of businesses

As healthcare facilities strive to reduce operating expenses, improve clinical efficacy and "go green," the need to sterilize Orthopaedic and Spine instrument sets in a rigid container system versus the traditional blue wrap is dramatically increasing. Aesculap, the preferred choice of customers worldwide for rigid sterile containers, has a support model for Orthopaedic and Spine vendors to meet the needs of the healthcare market.

Today Aesculap is a global company selling its products in more than 50 countries. As the recognized leader in quality, product development, production and change control are all tightly managed by Aesculap's corporate-wide Integrated Management System.

The Aesculap SterilContainer™ products are fixed in size and do not change year to year, therefore Orthopaedic and Spine manufacturers can standardize on the design of preconfigured sets to ensure form, fit and function today and in the future.

Aesculap SterilContainer products have received FDA 510(k) clearance for steam sterilization.

Two business models are available:

- User Purchase
- Business to Business

In either model, the first step in the process is for the manufacturer of the instrument set to validate the set in an Aesculap SterilContainer.



For the User Purchase Model, as the name implies, the user (healthcare facility) will purchase the SterilContainer products from Aesculap to containerize the instrument set. The Aesculap sales force will support and facilitate the sale.

The Business to Business model assumes the user healthcare facility is requesting the manufacturer of the instrument set to provide Aesculap SterilContainer products along with their instrument sets. The manufacturer will purchase SterilContainer products directly from Aesculap and provide them to the user healthcare facility. The manufacturer will determine the business terms with the user on the SterilContainer products.



Aesculap SterilContainer™

Features and benefits

Aesculap's SterilContainer products have defined the world's standard for rigid sterilization container systems for more than 30 years.



Aesculap SterilContainer Overview

Aesculap SterilContainer Systems are recognized by thousands of satisfied customers around the world for product quality, clinical efficacy and outstanding customer service, and hold the #1 market share position. Aesculap is a worldwide supplier of SterilContainer products and can support your business needs by providing a SterilContainer system your customer is already familiar with.

A SterilContainer can be defined as a rigid barrier with filters that allow penetration of the steam sterilant while maintaining a sterile boundary during transportation and storage.



Sterile Packaging

Disposable blue wrap and rigid sterile containers are the two main choices for sterile packaging.

Blue Wrap is a one time use product which is disposed after each use.

Aesculap SterilContainer products are made from aluminum, are reusable for many years and offer a virtually impenetrable barrier to tearing and ripping.

Manufactured in Aesculap's state-of-the-art production facility in Tuttlingen, Germany to exacting Aesculap quality standards.



Features and Benefits

Undisputed quality leader

The robust design and state-of-the-art manufacturing process ensures reliability and consistency of the shape, dimensions and integrity of every SterilContainer™ component.

Long service life

Meticulous design and manufacturing standards ensure consistent form, fit and function over a typical 10+ year service life.

Superior handling

Designed for clinical efficacy and easy handling so consistent performance is delivered to the O.R., keeping cases on schedule and minimizing costs.

The lid of the SterilContainer always contains a filter.

There are two types of SterilContainer bottoms:

- Solid, no filter in bottom of container (JK) series of product
 - Available for use in PreVac steam sterilization
- Perforated, filter in bottom of container (JN) series of product
 - Available for use in gravity or PreVac steam sterilization

Aesculap offers eight standard size families (based on length x width) of containers in various heights to accommodate different size sets. Aesculap will provide engineering drawings under a signed non-disclosure agreement to facilitate pre-configured set design.

Typically Orthopaedic and Spine sets are containerized in the Aesculap full size SterilContainer which is 23¼ inches long, 11¼ inches wide and available in various heights from 4¼ to 10½ inches tall.

Validations you can trust

Rigid sterile containers are categorized by the FDA as a class 2 device, hence validation is required. Aesculap performs validation testing in the most common forms of sterilization methods found in a hospital setting such as:

- Steam – Gravity, PreVac, Immediate Use
- EtO
- ASP STERRAD® and STERIS V-PRO™ systems

Validation testing performed in steam sterilization is performed with a representative general instrument set. The SterilContainer is loaded to a total weight of 35 lbs, SterilContainer plus instrument load.

Aesculap's SterilContainer system is cleared by the FDA under the following 510(k) numbers.



Keeping current on industry regulations means Aesculap can accelerate your time to market.

Aesculap FDA Clearance Summary

Aesculap SterilContainer™ System	FDA 510(k) Clearance
SterilContainer™ System for Steam Sterilization (Gravity & Pre Vacuum) and Ethylene Oxide (EtO)	K792558
SterilContainer™ System for Steam Pre Vacuum Flash	K053389
SterilContainer™ S System for Advanced Sterilization Products, STERRAD® systems	K040865 K093493
SterilContainer™ S System for Steris Amsco® V-PRO™ 1 and V-PRO™ 1 Plus Low Temperature Sterilization System	K093649
Aesculap Reusable Sterile Container Filter for Steam Pre Vacuum and Steam Pre Vacuum Flash	K041623
Aesculap SterilContainer™ with PrimeLine® Lid for Steam Pre Vacuum and Steam Pre Vacuum Immediate Use (Flash)	K073168

Quality Management

Aesculap, as the manufacturer of medical devices sold globally, is committed to the highest level of patient care. All Aesculap products are developed, manufactured and marketed under this principle. Related requirements and standards that Aesculap offers in this partnership (e.g. quality, regulatory, design and change control, drawings, manufacturing, etc.) apply to Aesculap's global manufacturing facility in Tuttlingen, Germany.

To ensure Aesculap's commitment to patient care, the "Integrated Management System" (IMS) has been implemented in the manufacturing facility in Tuttlingen, Germany. The IMS ensures the conformity with international standards and statutory regulations in order to fulfill the needs of our company and our partners. The IMS is a system that describes all management, business, development and support processes within Aesculap. The IMS is supported by the board of directors of Aesculap and applies for all employees, activities and processes.



Key objectives and goals of the Integrated Management System (IMS) that are important to our partners are:

- **Development / Design / Production / Change Control**

Product development, production and change control are all tightly controlled by Aesculap's corporate wide Integrated Management System. Our Business to Business partners will receive detailed documentation about Aesculap processes, standards and regulatory affairs on the Aesculap SterilContainer to build a long-term partnership.

- **Engineering Drawings**

Aesculap SterilContainer products are fixed in size and do not change year to year, therefore our Business to Business partners can standardize the design of preconfigured sets to ensure form, fit and function today and in the future. Aesculap will provide engineering drawings of our containers to facilitate preconfigured set design in an Aesculap SterilContainer.

- **Validation Support**

Aesculap USA will provide regulatory, technical and the marketing support to facilitate with the validation process of products in the Aesculap SterilContainer. This enables our partners to provide validated sterilization parameters of customized sets in an Aesculap SterilContainer to their customers.

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