Instructions for alternate Rigid Container Moist Heat Sterilization of non-sterile products in the Aesculap® Rigid Containers

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: www.paragon28.com/resources. Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

This booklet is designed to assist in using the Baby Gorilla®/Gorilla® Plating System, Monster® Screw System, Monkey Rings™ External Fixation System, Phantom® Hindfoot TTC/TC Nail System, and APEX 3D® Total Ankle Replacement System in Aesculap® Rigid Containers. It is not a reference for surgical techniques.

GENERAL DESCRIPTION
The Aesculap® SterilContainer System is a reusable rigid container system used for the packaging, transportation, and storage of instruments prior to, during, and after sterilization.

PRODUCT MATERIALS
The Aesculap® SterilContainer System is manufactured with Aluminium.

INTENDED USE
The Aesculap® SterilContainer System is a reusable sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider.

WARNINGS AND PRECAUTIONS

PRODUCT DESCRIPTION
The Paragon28® systems provided in a perforated steam sterilization case may be placed directly into Aesculap® SterilContainers. Testing has demonstrated the system, when processed in Aesculap® SterilContainer systems JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10^{-6} sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Paragon 28® does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap® rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap® SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer.

(https://www.aesculapusa.com/products/insructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash Sterilization of the Paragon 28® systems is not recommended.

Unless specifically labelled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labelling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s).

For complete indications for use for any of the below products please find that information at http://paragon28.com/ifus/

The below chart indicates products approved for use with the Aesculap® rigid containers:

Document	Description
P51-IFU-0001	Baby Gorilla®/Gorilla® Plating System
P20-IFU-X001	Monster® Screw System
P45-IFU-0001	Monkey Rings™ External Fixation System
P31-IFU-0001	Phantom® Hindfoot TTC/TC Nail System
P10-IFU-0001	APEX 3D® Total Ankle Replacement System

HANDLING AND STERILIZATION
Non-Sterile Product

Product that are presented in a tray are provided non-sterile. All non-sterile implants and instruments should be processed using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. For manual reusable instrument reprocessing instructions, refer to the Paragon 28® Instruction for Use (IFU) of each mentioned systems for – ***Instrument Reprocessing Instructions for Reusable Instruments***. For product information or to obtain a copy of the surgical technique manual and/or the Summary of safety and clinical performance, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	30 Min.

This method may be used for the following systems: Baby Gorilla®/Gorilla® Plating System, Monster® Screw System, Monkey Rings™ External Fixation System, Phantom® Hindfoot TTC/TC Nail System, and APEX 3D® Total Ankle Replacement System.

PRODUCT COMPLAINTS
The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact Paragon 28®, Inc for product inquiries, cleaning instructions and surgical techniques. To report any adverse event, please contact Paragon 28 ®, Inc.

Paragon 28, Inc.
14445 Grasslands Dr.,
Englewood, CO 80112
USA
(+1) (855) 786-2828