Symbols on product

Not for use in intended applications as defined by the manufacturer

Attention, see instructions for use

Intended use
The ABC temporary fixation pins are part of the Aesculap ABC System for anterior cervical fusion. They are used for fixing ABC plates on the cervical vertebral body. They hold the ABC plates in position until the ABC screws are applied.

Materials
The ABC temporary fixation pins (US33R) are made of stainless steel according to ISO 7153-1.

Safe handling and preparation

CAUTION
Federal law restricts this device to sale by or on order of a physician

The ABC temporary fixation pins are designed for single use only; they are supplied in unsterile condition.

Note
Unused fixation pins can be reprocessed several times.

➢ Prior to its intended use, the ABC temporary fixation pin must be correctly inserted in its appropriate place in the storage device.
➢ Only prepare unused or new ABC temporary fixation pins in the storage device.
➢ ABC temporary fixation pins may only be used in combination with Aesculap ABC plate holding and fixation instrument P(828R and ABC pin insertion and extraction instrument P(858R.
➢ Read, follow, and keep the instructions for use.
➢ Use the product only in accordance with its intended use, see Intended use.
➢ Clean the new product either manually or mechanically prior to initial use. Always follow the manufacturer’s instructions regarding concentration, temperature and exposure time.
➢ Avoid encrustation of residues/proteins (e.g. caused by aldehyde/alcohol). Only use bactericidal, fungicidal and virucidal disinfecting agents.
➢ Preferably use thermal disinfecting processes.

Mechanical cleaning/disinfecting
➢ Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
➢ Process the product in a cleaning/disinfecting machine. Follow the instructions provided by the manufacturer of the machine.
➢ Processing cycle:
  - Use a temporary alkaline cleaning/disinfecting agent according to manufacturers’ instructions.
  - Do not exceed the maximum washing temperature of 55 °C.
  - Wash the product for at least 10 min.
  - Neutralize if necessary.
  - Carry out intermediate rinse for at least 1 min. (e.g., with fresh water at 93 °C).
  - Carry out intensive final rinse with distilled, desalinated or fully desalinated water.
  - For thermal disinfection: Rinse with distilled, desalinated or fully desalinated water for 10 min. or 93 °C.
  - Conclude the program with a drying period of at least 40 min at a temperature not exceeding 110 °C.
➢ After completion of the mechanical cleaning/disinfecting cycle, inspect all surfaces, cavities, lumens, and openings for visible debris.
➢ Carry out additional manual cleaning if necessary.

Manual cleaning/disinfecting
➢ Use a suitable alkaline cleaning/disinfecting agent according to the manufacturer’s instructions. Immers the product in the cleaning/disinfecting agent in such a way that all surfaces, cavities, lumens and openings are covered.
➢ After the end of the disinfection period, thoroughly rinse the product under running water, making certain water flows through every lumen and channel, and all blind holes are repeatedly filled and drained.
➢ Remove encrusted debris with a soft plastic brush. Do not use harsh cleaning agents or metal brushes.
➢ Carry out intensive final rinse with distilled, desalinated or fully desalinated water.
➢ Inspect surfaces, cavities, lumens and openings for visible debris. If necessary repeat the cleaning/disinfecting process.
➢ Use a lint-free cloth or a compressed-air gun for drying the product.

Control, care and inspection
➢ Allow the product to cool down to room temperature.
➢ Inspect the product after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, and not damaged (e.g., insulation), and does not have any loose, bent, broken, cracked, worn, or fractured components.
➢ Check for compatibility with associated products.
➢ Set aside the product if it is damaged.

Packaging
➢ Sort the product into its appropriate storage device or put it on a suitable tray. Make sure that all cutting edges are protected. Observe the weight limit for each tray/container.
➢ Package trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
➢ Insure that the packaging will prevent recontamination of the product in the period between reprocessing and reuse.

Sterilization method and parameters
➢ Make certain that all external and internal surfaces will be exposed to the sterilizing agent (e.g. by opening all valves and faucets).
➢ Apply steam sterilization, observing the following rules:
  - Sterilization has to be performed in a validated steam sterilization process (e.g. in a sterilizer according to EN 285/ANS/AAMI/ISO 11140-1993, ANSI/AAMI/ST746-1993, validated according to EN 554-ISO 13863). For the fractionated vacuum process, sterilization has to be carried out running the 134 °C-9-bar program for a minimum holding time of 5 minutes.
  - When sterilizing several products at the same time in one steam sterilizer, make sure that the maximum allowable load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.

For service, maintenance or repairs, contact your national B. Braun/Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantees/warranty rights and forfeiture of applicable licenses.

Service addresses
Aesculap Technischer Service Am Aesculap-Patz 78032 Tuttingen / Germany Phone: +49 7461 23-200 Fax: +49 7461 23-2887 E-mail: ats@aesculap.de
Or in the US:
Aesculap Inc. Attn: Aesculap Technical Services 615 Lambert Points Drive Hazlewood, MO 63042 Aesculap Repair Hotline Phone: +1 800 234-3392 Fax: +1 314 895 4420
Other service addresses can be obtained from the addressed indication above.

Distributor in the US/Contact in Canada for product information and complaints
Aesculap Inc. 3773 Corporate Parkway Center Valley, PA 18034 USA