Instructions for Use
Quintex™ Cervical Plating System

PRODUCT DESCRIPTION
The Quintex™ Cervical Plating System consists of the following components:

- Hybrid cervical plates
- Dynamic cervical plates
- Semi-constrained bone screws
- Constrained bone screws
- Dynamic bone screws
- Related implantation and explantation instrumentation

CONTRAINDICATIONS
Do not apply in the presence of:

- Fever
- Infection
- Systemic
- In the spine
- Local
- Pregnancy
- Acute osteoporosis
- Medical or surgical conditions that could negatively affect the success of the implantation
- Foreign body sensitivity to the implant materials
- Inadequate patient compliance
- Severe osteoporosis or similar loss of bone density
- Severe damage to bone structures that would prevent the stable implantation of system components
- Bone tumor in the region of implant fixation
- Anticipated excessive load on the joint implant
- Dependency on pharmaceutical drugs, drug abuse or alcoholism
- Systemic or metabolic disease(s)
- Morbid obesity (adiposity)
- Generally poor condition of the patient
- Wound healing disorders
- Neuromuscular diseases or disorders
- Mental illness
- Patients with a known or suspected nickel allergy may be sensitive to this device, as nickel is present in the Phynox material.

Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

MATERIALS
The Quintex™ Cervical Plating System is intended for the immobilization and stabilization of the spine as an adjunct to fusion in patients with:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e. fracture or dislocation),
- Spinal stenosis,
- Deformity (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumors,
- Pseudoarthrosis as a result of failed spine surgery,
- Failed previous fusions,
- Symptomatic cervical spondylosis
- Instability following surgery for the above indications.

WARNING
This device is not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

WARNING
The regulatory approval of the Quintex™ Cervical Plating System implants is predicated upon test results using system implants together with system instruments. Aesculap Implant Systems cannot be held liable for problems encountered where implants or instruments from other manufacturers are used in combination with Aesculap products.

PRECAUTION
Mixing of stainless steel implants with unalloyed titanium, titanium alloy, and other cobalt alloy implants should be avoided for implants that are in contact with each other.

PRECAUTION
The Quintex™ Cervical Plating System has not been evaluated for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.

CARE AND HANDLING
The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

1. PRE-CLEANING
Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Disassemble components to expose all surfaces and clean separately. Disassemble the component parts for the screwdriver, depth gauge and allagolt holder and any other instrument with component parts. Give special attention to joints and all parts to facilitate reassembly.

2. CLEANING
Cleaning Precautions

- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids.
- Do not exceed two hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

a. Manual Cleaning
Hand wash using a medical grade, low-sudsing, protein dissolving detergent. Follow the manufacturers’ directions regarding concentration, temperature, contact time and re-use.

Use a large syringe or pulsating water jet to thoroughly flush all channels and cavities with cleaning solution to remove debris.

Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

b. Ultrasonic and Mechanical Cleaning
For ultrasonic cleaning, follow manufacturer’s specifications for water level, concentration levels of cleaning agent and temperature.

When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other.

Always follow the manufacturer’s specifications for automatic washer-sterilizers and use a free-rinsing, low-sudsing detergent with a neutral pH (6.0 - 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal disinfection and cleaning.

Special attention should be given to lubrication of joints and movable parts. Only lubricate dry instruments. Do not use mineral oil, petroleum, or silicone-based products. To lubricate joints, use a non-silicone, water-soluble lubricant prior to sterilization, such as Aesculap Instrument Oil, JG50.

Rinse all instruments thoroughly with tap water, de-ionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal cavities and ratchets are thoroughly rinsed.

3. DECONTAMINATION
Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.

Select a proper product for high-level disinfection such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent’s recommended directions regarding concentration, temperature, contact time and solution re-use.

Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury.

5. LUBRICATION / ASSEMBLY
Lubrication is essential every time instruments are processed. Special attention should be given to lubrication of joints and movable parts. Only lubricate dry instruments.

5. STERILIZATION
Sterilization of implants and instruments is to be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of 10^-6, Aesculap recommends the following parameters:

Preconditioning Pulses: 4

Aesculap has validated the above sterilization cycles and has the data on file. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended methods are advised to validate any alternative method using proper laboratory techniques.
Instruments have also been validated for sterility in a STERILCONTAINER™ System at the above recommended cycle parameters.

Note: Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle, design, and packaging/containerization. The manufacturer’s instructions must be followed for each sterilization chamber.

STORAGE
Once the product is sterilized, it can be stored in the sterilcontainer.

MAINTENANCE AND REPAIR
If any Quintex Cervical Plating System instrument or its components require repair or maintenance, return the entire instrument set in a sturdy box with adequate foam, bubble wrap or other packaging material to protect it. Send the packaged instrument to:

Aesculap Technical Services
615 Lambert Point
Hazelwood, St. Louis, MO 63042

Instruments returned to Aesculap Implant Systems for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.