ORIO-Ti Intervertebral Body Fusion Cage System
INSTRUCTIONS FOR USE

CAUTION: USA law restricts this device to sale by or on the order of physician.

1. PRODUCT HANDLING

The implants used as a part of this system are provided nonsterile. Instruments are provided nonsterile. Non-sterile implants and instruments should be stored in their original packaging or placed within the sterilization container provided. Implants and instruments should be stored in such a manner when not in use, and until they are cleaned and sterilized according to the recommended guidelines listed below. Protect implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

2. PRODUCT DESCRIPTION AND IMPLANT MATERIALS

The ORIO-Ti intervertebral body fusion Cage is a single component spinal device manufactured from titanium alloy conforming to ASTM F136 specifications. The implant is available in a range of sizes, heights and lordotic angles to match more closely the patient's anatomy. The implants have cavities to accept packing of bone graft.

3. INDICATIONS

The ORIO-Ti cervical intervertebral body fusion cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. ORIO-Ti cervical intervertebral body fusion implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. ORIO-Ti cervical intervertebral body fusion implant is to be used with supplemental fixation that has been cleared for use in the cervical spine.

ORIO-Ti lumbar intervertebral body fusion cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had at least six (6) months of non-operative treatment. ORIO-Ti lumbar intervertebral body fusion implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft and implanted via a transforaminal, open posterior, anterior/anterolateral, or lateral approach. The ORIO-Ti lumbar intervertebral body fusion implants are to be used with supplemental fixations that have been cleared for use in the lumbosacral spine.

4. PATIENT SELECTION.

In selecting patients for intervertebral body fusion devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. **The patient's occupation or activity**. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

B. **A condition of senility, mental illness, alcoholism, or drug abuse**. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

C. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

D. **Foreign body sensitivity**. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

E. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

5. PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Only legally marketed, and locally approved sterilization barriers (e.g. wraps, pouches or rigid containers) should be used for packaging terminally sterilized devices, in compliance to the manufacturer's instructions. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface. Damaged packages or products should not be used, and should be returned to SpineCraft.

6. CLEANING AND DISINFECTION

LIMITATIONS AND RESTRICTIONS

POINT OF USE CARE:

- Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled.
- Minimal handling of implants is necessary to prevent damage to the surface.

CONTAINMENT AND TRANSPORTATION:

- Implants should not come in contact with soiled devices and/or equipment.
- Avoid cross contamination of implants with soiled instruments during transport.

PREPARATION FOR PROCESSING:

- SpineCraft does not recommend the reprocessing of soiled implants.

MANUAL CLEANING / DISINFECTION PROCEDURE:

Equipment: ultrasonic cleaner, enzymatic cleaner or detergent solution, clean, soft, lint-free single-use cloth or medical grade compressed air. Use the following steps:

Step 1	Prepare a fresh detergent solution using enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. *Note: For the validation of the manual cleaning, the enzymatic cleaner ENZOL® (ASP, REF 2252) was used by SpineCraft in a concentration of 1 ounce per gallon tap water in an ultrasonic bath)*
Step 2	Clean SpineCraft implant ultrasonically for a minimum of 15 minutes.
Step 3	Rinse implant using DI or PURW water for a minimum of two minutes. DI or PURW water must be used for final rinse.
Step 4	Disinfect implants using 75% isopropanol. Hold time 10 min at 20°C.
Step 5	Dry implants using a clean, soft, lint-free single-use cloth or medical grade compressed air.

AUTOMATED WASHER CLEANING / DISINFECTION PROCEDURE:

Equipment: washer/disinfector (Type Miele PG8581 or equivalent), enzymatic cleaner or detergent solution. Use the following cycle parameters:

Step1	Pre-clean using cold tap water for 2 min.
Step 2	Clean using 0.5% cleaner at 55 °C for 5 min with demineralized water. *Note: For the validation of the automated cleaning, the Neodisher MediClean enzymatic mild alkaline cleaner detergent was use by SpineCraft.*
Step 3	Rinse with demineralized water for 1 min.
Step 4	Thermo-disinfection with demineralized water at 93 °C for 5 min.
Step 5	Dry implants using medical grade compressed air.

7. INSPECTION

- SpineCraft implants should be inspected after processing, prior to sterilization.
- Any implant with corrosion, scratches, flaws, residue or debris should be discarded.

8. STERILIZATION

ORIO-Ti Cage System implants are supplied clean and nonsterile; ASTM F565 or AORN recommended practices for in-hospital sterilization should be followed for all components.

All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of ORIO-Ti Cage System instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Blue Wrap: The wrap should be FDA cleared for the proposed cycle specifications.
Or
Reusable Rigid Sterilization Containers:
For the use of the Aesculap SterilContainer System for the sterile processing of ORIO-Ti implants and instruments, the contents of the ORIO-Ti implants and instruments cases must be transferred into an appropriate generic mesh basket and placed within the rigid container, according to all other applicable requirements in the Aesculap rigid container Instructions for Use.

Testing has demonstrated the ORIO-Ti Cage System, when processed in Aesculap JN443 and JK445 rigid containers (with corresponding JK490 lid and Aesculap single use filters US751 or US994), can be sterilized to a 10^{-6} sterility assurance level (SAL) in a pre-vacuum steam sterilization cycle when processed using the above listed sterilization parameters.

Ensure that the supplied reusable rigid sterilization container is clean and in proper working order prior to sterilization according to the manufacturer's Instructions for Use.

Aesculap rigid containers JN443 and JK445 have been validated ONLY with Aesculap single use filters US751 or US994. For the appropriate use of the proposed Aesculap SterilContainer System Extra Long Size, please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THESE 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.

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator. 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.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

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NOTE: SpineCraft does not recommend Flash Sterilization within instrument cases or Chemical Sterilization.

9. STORAGE

Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

10. CONTRAINDICATIONS

- Active sepsis;
- Pregnancy;
- Muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Conditions that place excessive demand on the implant (i.e. Charcot's joints, muscle deficiencies, refusal to modify post-operative physical activities, skeletal immaturity);
- Active infection in the area of proposed surgery;
- Severe osteoporosis;
- Paget's disease;
- Renal osteodystrophy;
- Advanced diabetes;
- Rheumatoid arthritis;
- Immunological suppression;
- Sustained trauma with instability;
- Fracture of the vertebra;
- Conditions requiring steroids in excess of usual doses;
- Obesity
- Signs of local inflammation,
- Fever or leukocytosis,
- Mental illness,
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count,
- Suspected or documented allergy or intolerance to composite materials,
- Any case not needing a fusion,
- Any case not described in the indications,
- Any patient unwilling to cooperate with postoperative instructions,
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery,
- These devices must not be used for pediatric cases, or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1,
- Any case where the implant components selected for use would be too large or too small to achieve a successful result,
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality,
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance,
- Prior fusion at the level to be treated
- See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING INTERVERTEBRAL BODY FUSION DEVICES section of this insert.

11. SAFETY & PERFORMANCE INFORMATION

Based on SpineCraft's Post-Market Surveillance data, including data from the Risk Management File, the user should note the following specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to intervertebral body fusion devices. General surgical risks should be explained to the patient prior to surgery.

A. IMPORTANT NOTE TO OPERATING SURGEON

The ORIO-Ti Intervertebral Body Fusion Cage System implants, like any other temporary intervertebral body fusion devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, dislodgement, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless break or dislodge. Therefore, the patient must be made aware that implant components may break or dislodge even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary intervertebral body support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used or if a pseudo-arthrosis develops.

The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using the ORIO-Ti intervertebral body fusion Cage System and should personally verify that all required implants sizes and necessary instruments are present before the surgery begins.

B. WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

SURGEON TRAINING AND EXPERIENCE The implantation of the Intervertebral body Fusion Cage should be performed only by experienced spinal surgeons with specific training in the use of this Intervertebral body Fusion Cage system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon.

SURGICAL IMPLANTS MUST NEVER BE REUSED. Although the device may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Familiarity with, and attention to the surgical technique recommended for this device is imperative for best results. The correct selection as well as the correct seating/placement of the implant is extremely important. SpineCraft instruments and implants should only be used in conjunction with other SpineCraft instruments and implants. The surgical technique may be obtained from the company or its representative.
Care must be taken to protect surfaces from nicks and scratches that could become focal points for failure. An implant must not be tampered with, as tampering could adversely affect the performance of the implant.

Surgical technique brochures are available upon request. Before the initial use of the ORIO-Ti intervertebral body fusion Cage System, the surgeon should review all available information and consult with other surgeons having experience with these types of devices. The surgeon should be thoroughly familiar with the assembly of the components.
The implantation of two devices of the same size at each targeted level is recommended in case of posterior lumbar interbody fusion.

IMPLANTS FATIGUE. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that an implant is not as strong as normal healthy bone and could loosen, dislodge and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation. The patient must be instructed in the limitations of the implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

PREVIOUS SPINAL SURGERY. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

IMPLANT SELECTION. The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or dislodgement of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION. Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by SPINECRAFT. In the interests of patient safety, it is therefore recommended that SPINECRAFT implants are not used with devices from any other source. Never, under any circumstances, reuse an ORIO-Ti Intervertebral body Fusion cage System device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

COMPATIBILITY: Components from two different systems should not be mixed.

MAGNETIC RESONANCE (MR) SAFETY: The ORIO-Ti Cage System has not been evaluated for safety and compatibility in the MR environment. The ORIO-Ti Cage System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ORIO-Ti Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

C. PREOPERATIVE PLANNING AND POSTOPERATIVE CARE

Preoperative planning provides essential information regarding the appropriate implant and likely combinations of components. Use instrument trial components for fit verification (where applicable) and extra implants for backup.
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Since mechanical parts are involved, the surgeon should be familiar with the various components before using ORIO-Ti Intervertebral body Fusion Cage System and should personally verify that all required implants sizes and necessary instruments are present before the surgery begins.

POSTOPERATIVE:

- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, dislodgement, and/or breakage of the device(s) are complications which

may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.

- The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components dislodge and / or break, the devices should be revised and / or removed immediately before serious injury occurs.
- ORIO-Ti Cage System implants are intervertebral body fusion devices and are intended to maintain intervertebral disc space height and contain bone graft during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.
- POSTOPERATIVE MOBILIZATION: Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.
- Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

D. POSSIBLE ADVERSE EFFECTS

- Cracking or fracture of the implants or loss of fixation in bone
- Early or late movement of the implant.
- Implant dislodgement or subsidence
- Metal sensitivity or allergic reaction to a foreign body.
- Infection, early or late.
- Loss of anatomic position with malunion
- Nonunion, delayed union
- Adjacent-Segment Degenerative Changes
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation in males, paraesthesia, or other types of serious injury.
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, reduction and/or intervertebral disc space height (subsidence).
- Bursitis.
- Paralysis temporary or permanent
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
- Device back out, possibly leading to implant loosening, and/or reoperation for device removal.
- Damage to lymphatic vessels and/or lymphatic fluid exudation.
- Spinal cord impingement or damage.
- Non-union (or pseudoarthrosis)
- Degenerative changes or instability in segments adjacent to fused vertebral levels.
- Fracture of bony structures or stress shielding at, above, or below the level of surgery.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Spinal epidural hematoma.
- Inability to resume activities of normal daily living.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
- The risk of device expulsion and migration is higher without the use of supplemental fixation.
- Death.

E. PRODUCT COMPLAINTS

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, SpineCraft or our Authorized European Representative. Further, if any of the implanted ORIO-Ti Cage System component(s) ever “malfunctions”, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any SpineCraft product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s) or product UDI, your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

LIMITED WARRANTY AND DISCLAIMER: ORIO-Ti CAGE PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at:
+1 630-920-7300.

SURGICAL TECHNIQUE MANUAL COULD BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

Symbols:

Lot Number

Catalog Number


Single Use


Attention, see instructions for use

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