Instruction for use, please read prior to use

INSTRUCTION FOR USE OF ORTOVIA EXTERNAL FIXATION SYSTEM

DESCRIPTION & INDICATIONS FOR USE

Ortovia External Fixation System consists of a series of monolateral, Hybrid and circular external fixators intended to be used in conjunction with Ortovia Shanz Screw, Krishner wire.

These devices are intended as a means to stabilize bone segments in a broad range of indications, including

1.fractures,

2.joint fusion,

3.joint distraction,

4.bone transport, lengthening and angular corrections.

The Ortovia External Fixation System components are not intended to replace normal healthy bone or to withstand the stresses of full weight bearing, particularly in unstable fractures or in the presence of non union, delayed union or incomplete healing. The use of external supports (e.g. walking aids) is recommended as a part of the treatment. The system consists of various modules to be applied in different anatomical sites, i.e. tibia, femur, pelvis, humerus, forearm, hand and foot. When used correctly, the Ortovia External Fixation System maintains limb function, minimizes surgical trauma to anatomical structures, preserves the blood supply and osteogenic potential of the tissues, and where indicated, provides for the application of dynamization to enhance the fracture healing process. All Ortovia devices are intended for professional use only. Surgeons who supervise the use of Ortovia devices must have full awareness of orthopaedic fixation procedures as well as adequate understanding of the philosophy of the Ortovia modular system. To promote the proper use of its fixation system, and establish an effective promotional and training tool, Ortovia has developed several manuals or CD-ROM's containing the relevant information (i. e. general philosophy, surgical application, etc.) called "Operative Techniques". These are available in diffirent languages as a complimentary service for surgeons who have adopted the Ortovia External Fixator system. If you wish to receive a personal copy, please contact Spinamer or its local authorized representative, with a description of the medical device to be used. Additionally technical support can be asked to Spinamer or the dealers prior or during surgery.

CONTRAINDICATIONS

The Ortovia External Fixation System is not designed or sold for any use except as indicated. Use of the system is contraindicated in the following situations:

1.Patients with mental or physiological conditions who are unwilling or incapable of following postoperative care instructions.

2.Arthrodiatasis of the hip utilizing Ortovia external fixation in inflammatory arthropathies and for patients over the age of 45 years.

3.Patients with severe osteoporosis, patients who are HIV positive and patients with severe, poorly controlled diabetes mellitus.

4.Patients with foreign body sensitivity. Where material sensitivity is suspected, tests should be made prior to implant insertion.

WARNINGS & PRECAUTIONS

1.Compression is never recommended in a fresh fracture.

2.Axial displacement may occur if the body of the fixator is not in line with and parallel to the bone.

3.Medial or lateral translation may occur if the body of the fixator is not placed parallel to the diaphysis

4.Particular care should be taken that screws do not enter the joints or damage the growth plates in children.

5.Dynamization and physical therapy guidelines should be followed based on each individual case and the fixation system used, and should be instituted as and when considered appropriate by the surgeon, in accordance with clinical and radiological findings.

6.Any device implanted into the patient, such as bone screws, Kirschner wires, and in general any device which is labelled "single use only", including any part of any external fixation device, must not be re-used.

7.Screw length and thread length should be selected in accordance with bone and soft tissue dimensions. The screw thread is conical in design and tapers, for example, from 6.0 to 5.0mm between the shaft and the tip of the standard Ortovia screws, Thread length should be such that at least one full thread will remain outside the entry cortex and the screw tip will project just beyond the second cortex. Screw thread lengths are provided in increments of

10mm, so that no more than 10mm of thread should be exposed outside the entry cortex. Excessive penetration of the second cortex by any type of screw should be avoided, because of the risk of soft tissue damage. Bone screws should never be inserted so that the smooth shank penetrates the entry cortex, because of the risk of damage to the bone.

8.Due to the conical thread design, any attempt to back out an Ortovia screw once it has been inserted may cause it to become loose.

9.Screw diameter should be selected in accordance with bone diameter: for a bone diameter greater than 20mm, 6-5mm bone screws should be used; for a bone diameter between 12 and 20mm, 4.5-3.5mm bone screws; and for a bone diameter between 9 and 12mm, 3.5-3.2mm bone screws should be used.

10.For pre-drilled bone screws, pre-drilling with appropriate drill bits and drill guides prior to screw insertion is imperative. Matching grooves on screws and drill bits help the surgeon to use the correct drill bit. Blunt drill bits can cause thermal damage to the bone and should always be discarded.

11.Self-drilling screws with a thread diameter of 5.00mm or above should never be inserted with a power tool, but always by hand or with a hand drill. Self-drilling screws with smaller thread diameters may be inserted with a power drill at low speed.

12.When cutting the bone screws, they should either be cut before insertion, or after they have all been inserted, the fixator applied and the clamp locking screws firmly tightened. They should never be cut after insertion before the fixator is applied, because some of the cutting force may be transferred to the bone.

13.The Ortovia bone screws are designed to be self-drilling, and direct insertion with a hand drill is advised in most cases. However, when insertion of self-drilling screws is performed in diaphyseal bone, pre-drilling is recommended; use a 4.8mm drill bit through a drill guide when the bone is hard; when the bone quality is poor, or in the metaphyseal region where the cortex is thin, a 3.2mm drill bit should be used. Screw insertion, whether or not pre-drilling has been performed, should always be with the hand drill or T-Wrench only. It is important that moderate force is applied for the screw to gain entry into the first cortex. Insertion can be completed with the T-wrench.

14.Diaphyseal bone screws should always be inserted in the centre of the bone axis, to avoid weakening it. In all cases the surgeon should be mindful of the amount of torque required to insert the screw. If it seems tighter than usual, it is safer to remove the screw and clean it, and drill the hole again with a 4.8mm drill bit, even if it has already been used.

15.Transfixing pins of 4mm in diameter are self-drilling and may be inserted with a power drill. These pins are used in association with the Viafix Rapid Fixator for temporary ligamentotaxis of the ankle and knee. After insertion they should be cut and the ends protected so that the patient cannot be injured on the opposite leg. Ortovia Transfixing pins are single use devices and should never be re-used. They are connected to the Bars with two holders.

16.When screws are to be held in one of the range of 3 or 5 seat screw clamps, it is very important that they are inserted with the correct procedure, so that they are parallel when in position. This is achieved by using screw guides in the templates or fixator clamps provided, and pre-drilling the screw hole, when required, through the correct size of drill guide. The clamps should be tightened so that the screw guides are gripped evenly, and held in correct relationship to each other.

17.When screws are inserted into one of the fixator clamps, in such a way that one of the screw seats at the end of the clamp is empty, it is important that this is filled with a short, dummy screw, so that the clamp cover grips all the screws with an equal pressure.

18.The T-Clamp of the Ortovia External Fixator allows for either parallel or convergent positioning of the proximal screws. When using the T-clamp, the first screw to be inserted should always be in the screw seat which is part of the fixed straight clamp; subsequent screws should be in the converging section of the T-clamp. When the convergent mode is used, the fixator should be positioned at the correct distance from the bone before inserting the second screw, as the fixator will not slide along convergent screws.

19.For more stable fixation of a fracture with a fixator, we recommend that the nearest bone screw is applied fairly close to the fracture margin (a minimum of 2 cm is

recommended) and that these distances are equal on both sides of the fracture. The supplementary screw holder is supplied to achieve this.

20.When unusually high loading conditions are likely, such as weight bearing with a femoral application or when the patient is very heavy, before the ball joints are locked the fixator body should be aligned so that the body locking nut is at 90 degrees to the plane of the screws. In addition for increased stability the clamp may be moved onto the joint to transfer the load from clamp to the body to by-pass the joint.

21.No attempt should be made to insert a Kirschner wire more than once; since the tip may have become blunt and is the only cutting surface, undesirable heating of the bone may occur.

22.Appropriate Ortovia instrumentation should be used to insert bone screws and Kirschner wires correctly.

23.Wherever a Kirschner wire or Guide Wire is used to guide a cannulated reamer, drill bit or screw into position:
The Kirschner or Guide Wire should always be NEW.

24.The wire should be checked before insertion to exclude any scratches or bends.

25.During the introduction of any instrument or implant over a wire, the surgeon should screen the wire tip as continuously as possible to exclude inadvertently driving the wire further than intended.

26.During each pass of the instrument or implant, the surgeon should check that there is no bony or other debris built up on the wire or inside the instrument or implant which might cause it to bind on the wire and push it forward.

27.It is impossible to clean the inside of a cannulated drill bit adequately to exclude organic or other debris remaining after use.
CANNULATED DRILL BITS SHOULD THEREFORE NEVER BE REUSED. THEY ARE SINGLE PATIENT USE ONLY.

28.If a cannulated drill bit is to be used for a second time on the same patient, the surgeon must check that the drill bit is free from obstruction, by removing it from the power unit and passing a wire through it.

29.Even when a cannulated drill bit is new, we recommend that a wire is passed through it prior to use, to check that the lumen is free from obstruction.

30.Ortovia ring fixator has Shanz-wire holder to fix the shanz screw and the Kirschner wires.

31.To tension Kirschner wires, the wire tensioning device should be used and wires mounted on a circular ring should be tensioned between 800-1000N.

32.Tension should be reduced to 800-1000N when Kirschner wires with a central olive are used to stabilize a fragment.

33.All equipment should be carefully examined prior to use to assure proper working condition. If a component or instrument is believed to be faulty, damaged or suspect, it should NOT BE USED. Hybrid Fixation Frames for use in progressive deformity correction should be pre-assembled and tested prior to application to ensure that they will provide the desired correction and that the joints are at the correct level.

34.The fixator should be applied at a sufficient distance from the skin to allow for post-operative swelling and for cleaning, remembering that the stability of the system depends upon the bone-fixator distance. If the fixator is sited at a distance of more than 4 cm from the bone, the use of 3 screws per clamp is advisable.

35.Final locking of the ball-joints of the Ortovia Fixatorrs is performed with a torque wrench, which must be turned in a clockwise direction only. A click indicates that the correct torque has been applied. Any attempt to unlock the cam or any screw using the torque wrench will damage its gearing. The torque wrench is pre-set at a specific value, which is 25 Nm±0.5). This value should be checked at least every one years or any time the instrument becomes damaged, by returning it to the local authorized representative.

36.Components may not be interchangeable between all models of Ortovia external fixation systems. Consult individual operative technique guides for interchangeable components.

37.When an unstable fracture is treated with the Hybrid fixator, weight bearing must be prevented up to enough bony support achievement.

38.Additional equipment may be required for fixation application and removal such as wire cutters, mallet and power drill.

39.Screw and frame integrity should be monitored at regular intervals.

40.Meticulous screw or wire site hygiene is required.

41.All patients must receive instruction on the use and maintenance of their fixator, and on pin site care.
42.Patients should be instructed to report any adverse or unanticipated effects to the treating surgeon.
43.The fracture site gap should be reassessed periodically during healing, and adjustments to the frame made as necessary. Persistent separation of the fracture ends may lead to delay in bone union.
44.In patients undergoing distraction osteogenesis, the rate of distraction (usually 1mm per day, i.e. 1/4 turn of the compression-distraction unit every six hours) should be controlled and adjusted in accordance with the rate of ossification, monitored radiologically.
45.**Removal of the device**: the surgeon should make the final decision whether a fixation device can be removed.
46.Do not use components of the Ortovia External Fixation Systems in conjunction with products of other manufacturers, unless otherwise specified, as the combination is not covered by the necessary validation.

During Wire insertion:

46.When Kirschner wires are inserted for use with a ring based frame, whether hybrid or a full circular frame:
They should be inserted from the side where the soft tissues are at most risk
47.They should be tapped through the soft tissues and drilled through the bone; they should never be drilled through soft tissues
48.They should be inserted with full knowledge of the safe corridors to avoid damage to the vital structures (see operating manuals)
49.A wire that has been inserted once should always be discarded if it is removed before tensioning (the tip may have become blunt and is the only cutting surface, so undesirable heating of the bone may occur)
50.Wire ends should be protected so that the other limb is not injured, either with covers firmly mounted, or by bending the ends over towards the ring.

Hybrid or full ring frames:

FULL LOAD SHARİNG MUST NOT BE ALLOWED. If the fracture is unstable, so that full load sharing is im possible.
51.Where necessary, a supplementary bone screw should be used to equalise the distance between the fracture and the nearest fixation point on both sides.
52.During screw or wire insertion care should be taken to avoid the soft tissues becoming attached to the screw or wire.
53.Rings should be assembled so that the 1/3 components, or the spaces where a 2/3 ring is used alone, are above each other.
54.The space in a 2/3 ring, or the 1/3 component of a complete ring, should always be positioned posteriorly.
55.Ideally all rings should be the same size; the frame should be applied so that the whole leg, not just the bone, is in the centre of the ring, and it is possible to insert two fingers between ring and soft tissues for the full circumference.
56.Each ring should be at 90 degrees to the axis of the bone segment to which it is applied.
57.For ideal stability in all planes, there should be an angle between the outer two wires (crossing angle) of about 60 degrees. This is achieved by shanz-wire holder is moved in its channel on the ring.
58.Each bone segment should be supported by 3 or 4 tensioned wires or shanz screws which can all be mounted on one ring.

POSSIBLE ADVERSE EFFECTS

1. Nerve or vessel damage resulting from insertion of wires and screws.
2. Superficial or deep bone screw tract infection, osteomyelitis, or septic arthritis, including chronic drainage of bone screw sites after device removal.
3. Oedema or swelling; possible compartment syndrome.
4. Joint contracture, subluxation, dislocation or loss of range of motion.
5. Premature bone consolidation during distraction osteogenesis.
6. Possible tension to soft tissues and/or frame during callus manipulation (i.e. correction of bony deformity and/or bone lengthening),
7. Failure of bone to regenerate satisfactorily, development of nonunion or pseudarthrosis.
8. Fracture of regenerate bone or through bone screw holes after device removal.
9. Loosening or breakage of the bone screws.
10. Bony damage due to inappropriate bone screw selection.

11. Bone deformity or equinus of the foot.
12. Persistence or recurrence of the initial condition requiring treatment.
13. Reoperation to replace a component or entire frame configuration.
14. Abnormal growth plate development in patients who are skeletally immature.
15. Foreign body reaction to bone screws or frame components.
16. Tissue necrosis secondary to bone screw insertion.
17. Pressure on the skin caused by external components when clearance is inadequate.
18. Limb length discrepancy.
19. Excessive operative bleeding.
20. Intrinsic risks associated with anesthesia.
21. Intractable pain.
22. Bone sequestration secondary to rapid drilling of bony cortex with heat build-up and bone necrosis.
23. Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis.

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

CAUTION

When the normal sensation of the limb is disturbed, so that the patient will not receive the normal proprioceptive feedback, any fixation system may be subject to above normal loads. In such circumstances the patient should be warned about the risk of excessive loading of the fixation device, and the physician should be on the lookout for particular problems related to excessive loading, such as loosening, bending or breakage of components. It is recommended in these situations that the fixation system is constructed to be more robust that might otherwise be required.

Important

A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure which require further surgical intervention to remove or replace the external fixation device. Preoperative and operative procedures including knowledge of surgical techniques and proper selection and placement of the external fixation devices are important considerations in the successful utilization of Ortovia external fixation devices by the surgeon. Proper patient selection and the patient's ability to comply with physician instructions and follow prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations. If a surgical candidate exhibits any contraindications or is predisposed to any contraindications, DO NOT USE Ortovia external fixation devices.

Materials

The Ortovia External Fixation System is comprised of titanium alloy or stainless steel, aluminium alloy and composit components. Those components which contact the patient are the percutaneous pins (bone screws), K-wires, drill bits, guides used during screw insertion, trocars and bone depth gauges. These are manufactured from surgical grade stainless steel. Some of the Ortovia external fixation bone screws (pins) are supplied with a thin, plasma sprayed coating of hydroxyapatite (HA) on the threaded portion of the shaft.

Non-Sterile

Ortovia external fixation components are provided NON-STERILE. Ortovia recommends that all NON-STERILE components be properly cleaned and sterilized following the recommended cleaning and sterilization procedures.

Product integrity and performance are assured only if packaging is undamaged.

Cleaning & Maintenance

Prior to use, NON-STERILE product must be cleaned according to validated procedure of the hospitals.

To prevent corrosion, the components must be kept dry, and detergents with fluoride, chloride, bromide, iodide or hydroxyl ions must be avoided when cleaning, as they will damage the anodised coating on any Ortovia products, and this may initiate the process of stress corrosion.

Before sterilization, all components should be inspected, since damage to the surface of metal components can reduce strength and fatigue resistance, and may lead to corrosion. If components are damaged in any way, they should be exchanged immediately for new ones. Assembly

of the fixator should then be carried out to ensure that all components are present.

Note: All parts and unit of Ortovia are for SINGLE USE ONLY.

ORTOVIA IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE FIRST PATIENT USE OF SINGLE USE DEVICES. The institution or practitioner bears full responsibility for any subsequent use of these devices.

Sterilization

The sterilization must be done according to validated sterilization method of hospitals according to table presented below:

Method	Cycle	Heat	Exposure time	Drying time
Steam method.1	gravity	132°C(270°F)	15min	30min
Steam metho.2	Pre vacuum (min 4puls)	132°C(270°F)	4min	30min

If The fixator is sterilized in the assembled state, the ball-joints, central body locking nuts and clamp locking screws MUST BE left untightened. Sterilisation of the fixator with one or more joints locked is highly likely to cause cracking. The Sterilization tray must be used for sterilization. Sterility cannot be assured if the sterilization tray is overloaded. Do not overload the sterilization tray or include additional implants or instruments from any source. If the fixator is not implanted, ıt can be re-sterilized.

CAUTION:

Care should be taken that LEGAL RESTRICTION in some countries may be present for this device to be sold by or on the order of a physician.

Storage and Trasport:

Ortovia must be stored and transported in special metal container or packages. Any biological, physical or chemical contaminants must be eliminated.

Traceability:

There is always a lot number on the label of each Ortovia External Fixator product. This lot number must be attached to the file of the patient in order to trace back production procedures. Because of traceability reason, distributional documents have to be maintained for 5 years.

Notification:

The following must be assured.

1. Delivery:

Particular requirement for active implantable medical devices and implantable medical device;

The supplier shall ensure that the name and address of the shipping package consignee is included in the quality records (see 2).

2. Control of quality records:

Particular requirements for all medical devices;

The supplier shall retain the quality records for a period of time at least equivalent to the lifetime of the medical device as defined by the supplier, but not less than 2 years from the date of dispatch from the supplier.

3. Ordering Information:

Ortovia can be ordered from your distributor or contact with Spinamer

4. Disposal:

Dispose Ortovia after removal as medical wast according to local regulations.

5. Symbols:

LOT	Batch code	NON STERILE	Non-Sterile
REF	Catalogue number		Consult instructions for use
	Do not reuse		Warning: See İnstructions for use
	Manufacturer		

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