Biodynamik, Inc.
XT3 System
Instructions for Use

PRODUCT DESCRIPTION / INTENDED USE

The XT3 System is a unilateral external fixator designed for skeletal fixation. It consists of a fixator, half pins, and specialized instrumentation for secure bone fixation. This single-use device is intended for transverse distraction and compression movement of a bone segment or expansion of soft tissue, including applications involving bone transport and correction of bony or soft tissue defects, and offers 3mm, 4.5mm and 5mm diameter half pins for versatile fixation options.

INDICATIONS FOR USE

The Biodynamik XT3 System is indicated for fracture fixation, nonunion and transverse bone transport of the tibia and the correction of bony or soft tissue defects or deformities in adults.

CONTRAINDICATIONS

The Biodynamik XT3 System is not designed or sold for any use except as indicated. Use of the system is contraindicated in the following situations:

- Patients with metal allergies and sensitivities.
- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely install the device.
- Patients unwilling or incapable of following postoperative care instructions.

INTENDED PATIENTS

Proper patient selection and the patient's ability to comply with physician instructions and follow the 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. The XT3 system is intended for adult patients.

INTENDED USERS

This product is intended for use by healthcare professionals (HCPs) who are fully trained in orthopedic procedures. Users must have a thorough understanding of the device, instruments, and surgical techniques, including both installation and removal.

NOTES FOR USE – DEVICE REMOVAL

Once the external fixation treatment is complete, the device must be removed. Healthcare professionals should evaluate early removal if adverse events occur.

DISCLAIMER

The HCP is fully responsible for the selection of the appropriate treatment and of the relevant device for patient (including post-operative care).

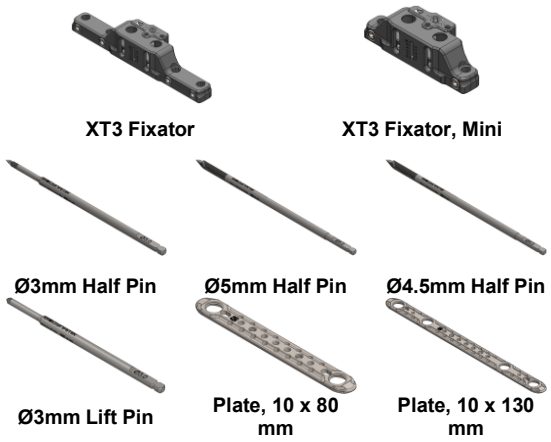
MODELS AND ACCESSORIES

The Biodynamik XT3 System is available in the models below.

Model Numbers and Description

Model Number	Description	System Components	Pin Size
XT3-000	XT3 System	XT3 Fixator Drill Guide Osteotomy Guide Stencil T20 Screwdriver 3.2mm Drill Sleeve 3.5mm Hex Key	(4) Static Pin Fixation: 5mm Half Pin (2) Intercalary Pin fixation: 3mm/4.5mm Half Pin
XT3-001	XT3 System, Mini	XT3 Fixator, Mini Drill Guide Osteotomy Guide Stencil T20 Screwdriver 3.2mm Drill Sleeve 3.5mm Hex Key	(2) Static Pin Fixation: 5mm Half Pin (2) Intercalary Pin fixation: 3mm/4.5mm Half Pin

XT3 System Components



WARNINGS AND PRECAUTIONS

- The XT3 System is supplied to the user with both sterile and non-sterile components.
  - Components that are supplied non-sterile and must be sterilized prior to use per the instructions provided. Failure to clean and sterilize the devices using the provided instructions could result in the device being non-sterile, which could cause a serious infection.
  - Components that are supplied sterile and should not be re-sterilized. Ensure that the protective packaging of the sterile components is unopened and undamaged; if the packaging is damaged, the components must be considered as NON-STERILE and may not be used.
- DO NOT REUSE or REPROCESS. This product is single-use only and intended for use on one patient during a single procedure.
- Reuse of single-use device may pose health and/or safety risks to the patient and surgeon that may include, and are not limited to cross-infection, breakage resulting in irretrievable fragments, compromised mechanical performance due to wear, loss of function and effectiveness of proper cleaning and sterilization.
- Modification or mishandling of the instruments will invalidate the functionality of the system and may result in improper function of the devices.
- Prior to use, all XT3 System components must be inspected where applicable for wear, damage, visible cleanliness, corrosion, and physical integrity of mechanical functions. If a device appears used or damaged, it should not be used.
- The XT3 fixator device should only be used with Biodynamik fixation pins.
  - The Half Pin shaft diameter for static fixation must be 5mm for proper compatibility with the XT3 fixator.
  - The Half Pin shaft diameter for intercalary fixation must be 4.5mm for proper compatibility with the XT3 fixator lifting plate.
- For transport procedures, a complete osteotomy must be verified. An incomplete osteotomy will prevent transport of the intercalary segment.
- Patients should restrict activities as directed by the physician until bone consolidation occurs.
- During the transport and docking phases, patient should not participate in contact sports or other high-risk activities. These activities may resume upon sufficient bone consolidation, but only as directed by the physician.

POSSIBLE ADVERSE EVENTS

In any surgical procedure, the potential for adverse reactions exists. Possible adverse effects particular to the XT3 System are listed below. These do not include all adverse effects which can occur with surgical procedures.

- Non-union, delayed union or malunion
- Superficial infection
- Deep infection
- Loss of fixation
- Bending, breakage or migration of the device
- Reoperation to replace a component or entire fixator configuration

- Bone fracture during or after treatment
- Damage to bone or surrounding tissues resulting from surgery or treatment
- Tension affecting the soft tissues and/or the fixator during callus manipulation
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Premature bone callus consolidation during distraction
- Wound healing complications
- Events caused by intrinsic risks associated with anesthesia and surgery

POSTOPERATIVE CARE RECOMMENDATIONS

PIN SITE CARE

Proper pin site care is essential to minimize infection risk and ensure successful treatment with external fixation.

- Clean pin sites daily using sterile techniques as recommended by the healthcare facility or per physician order.
- Apply sterile saline or an approved antiseptic solution to each pin site and gently remove crusts.
- Inspect for signs of infection or skin irritation, such as redness, swelling, tenderness, discharge, or foul odor.
- Dress pin sites with sterile gauze as instructed, keeping the area clean and dry.
- Report any symptoms of pain, swelling, or loose pins to a healthcare provider promptly.

OFF-LOADING AND OFF-LOADING STRATEGIES

Off-loading is recommended to reduce stress on the affected limb during bone healing and external fixation. Patients should follow the prescribed offloading strategies recommended by their surgeon. These may include:

- Use of a CAM walker boot, crutches, walker, or wheelchair to reduce limb loading and maintain mobility.
- Modification of daily activities to avoid placing stress on the limb until sufficient bone consolidation has occurred.

MRI (MAGNETIC RESONANCE IMAGING) SAFETY INFORMATION

Biodynamik has not evaluated the safety and compatibility of the XT3 System in Magnetic Resonance (MR) environment. No testing has been performed for heating or migration in the MR environment. The safety of the XT3 system in the MR environment is unknown.

PROCEDURES

Careful pre-operative planning and surgical technique are important considerations in the successful utilization of the Biodynamik XT3 System.

1. Perform visual inspection of all devices to ensure devices are intact and free of damage prior to cleaning and sterilization. Functional check should include ensuring mating instruments can be properly assembled and moving parts are operated to ensure correct operation.
2. For components that are supplied non-sterile, clean and sterilize according to the Cleaning and Sterilization Instructions provided below.

Manual Cleaning Instructions:

- Rinse the components under running RO/DI water.
- Dry all components using lint-free cloths and/or pressurized air.
- Perform visual inspection to ensure no particulate or debris is visible on devices, otherwise repeat rinse and dry steps.

Steam Sterilization Instructions:

Steam sterilization according to ANSI/AAMI ST79 is recommended. Use a validated, properly maintained, and calibrated steam sterilizer. Sterilize the XT3 System in a double-wrapped surgical tray using FDA-cleared sterilization wrap, following the sterilization parameters listed below.

Sterilization Type	Prevacuum
Preconditioning Pulses	4
Temperature	132°C
Full Cycle Time	4 minutes
Dry Time	30 minutes

3. Surgical Procedure – Transverse Tibial Bone Transport

3.1. Using the Stencil or the XT3 fixator, locate the desired anteromedial tibial location for placement of the XT3 fixator. Mark location of the Half Pins positions and the skin incision using a skin marker.

3.2. Make the skin incision medial to the planned location of the two intercalary Half Pins (3.0mm), centered between the outer Half Pins (5.0mm). Make dissection down to the bone, taking care to preserve the periosteum.

3.3. Retract the skin and place the Osteotomy Guide over the tibia. Using Ø2mm Drill Bits or K-wires, drill through the two center guide holes of the Osteotomy Guide through the tibia bicortically to prepare the pilot holes for the intercalary Ø3mm Half Pins and to provisionally secure the Osteotomy Guide to the bone.
- Following the proximal and distal series of holes on the Osteotomy Guide, drill through each perimeter guide hole with a Ø2.4mm Steinmann Pin to define the margins of the osteotomy through the tibia
- Use a 0.4mm sawblade to follow the longitudinal slots in the Osteotomy Guide to prepare the intercalary segment.

3.4. Slide the Drill Guide over the Osteotomy Guide. Using a Ø3.2mm Drill Bit, drill the remaining pilot holes for the Ø5mm Half Pins through Ø3.2mm Drill Sleeves placed in the outer fixation holes. Insert Ø5mm Half Pins through the pre-drilled holes. Alternatively, the self-drilling, self-tapping Ø5mm Half Pins can be inserted directly through the Drill Guide.

3.5. Remove the Drill Guide, Osteotomy Guide and Ø2mm Drill Bits or K-wires.

3.6. Proceed with the closure of the periosteum, subcutaneous tissue, and skin.

3.7. Slide the Drill Guide over the Ø5 mm Half Pins. Insert the Ø3 mm Half Pins through the Drill Guide and percutaneously thread into the intercalary bone segment for unicortical fixation. Do not insert the Ø3mm intercalary Half Pins deeper than 10mm, as bi-cortical fixation will prevent desired transport of the intercalary segment. Confirm proper placement of all intercalary Ø3mm Half Pins using fluoroscopy. Alternatively, a Ø4.5 mm Half Pin may be used for intercalary fixation.

3.8. Using the intercalary Ø3mm Half Pins, apply a forward and backward motion to break the remaining bone and completely mobilize the intercalary bone segment from the tibia. Remove the Ø2 mm drill bits or K-wires and the Osteotomy Guide.

3.9. Prior to installation of the XT3 fixator, insert the 3.5mm Hex Driver into the actuation screw and rotate clockwise (+ arrow) to confirm the actuation of the XT3 fixator. Rotate the actuation screw counter-clockwise (- arrow) to return the XT3 fixator to the original starting position. Slide the XT3 fixator over all the Ø5mm and Ø3mm Half Pins. Using the Drill Guide as a spacer, set the desired amount of soft tissue clearance between the bottom of the XT3 fixator and the skin. It is important to confirm equal spacing along the body of the XT3 to ensure the XT3 construct is both level and perpendicular to the Half Pins.

3.10. Tighten all set screws in the XT3 fixator with the T20 Screwdriver to secure the XT3 locking set screws to each of the Half Pins. Lock the outer static Half Pins prior to locking the inner intercalary Half Pins

3.11. To perform the transverse tibial bone transport, rotate the actuation screw clockwise (+ arrow) with the 3.5mm Hex Key to distract the intercalary segment. Rotate the actuation screw counter-clockwise (- arrow) with the 3.5mm Hex Key to retract the intercalary segment.

3.12. When usage of the device is complete, remove the XT3 fixator using the T20 Screwdriver to unlock all set screws in the XT3 fixator. Slide the XT3 fixator device off the Half Pins. Using a

Universal Chuck, remove the Half Pins by counterclockwise rotation. Discard all components of the XT3 fixator and Half Pins according to hospital guidelines.

4. **Surgical Procedure – General Fixation**
   - 4.1. Using the Drill Guide, locate the appropriate tibial location for placement of the XT3 fixator to align the intercalary Half Pins (5.0mm) positions with the desired stabilization points on the tibia.
   - 4.2. Insert the Ø3.2mm Drill Sleeve into the Drill Guide to aid drilling pilot holes for placement of the Ø5mm Half Pins.
   - 4.3. Insert Ø5mm Half Pins through Drill Guide into the pre-drilled holes. Confirm appropriate placement and bi-cortical fixation using fluoroscopy.
   - 4.4. Slide the XT3 fixator over the Ø5mm Half Pins. Using the Drill Guide as a spacer, set the desired amount of soft tissue clearance between the bottom of the XT3 fixator and the skin. It is important to confirm equal spacing along the body of the XT3 to ensure that the XT3 construct is both level and perpendicular to the Half Pins.
   - 4.5. Tighten all set screws in the XT3 fixator with the T20 Screwdriver to secure the XT3 locking set screws to each of the Half Pins.
   - 4.6. When usage of the device is complete, remove the XT3 fixator using the T20 Screwdriver to unlock all set screws in the XT3 fixator. Slide the XT3 fixator device off the Half Pins. Remove the Half Pins by counterclockwise rotation and discard all components of the XT3 fixator and Half Pins according to hospital guidelines.

5. Surgical Procedure – Ipsilateral Transport
   - 5.1. Using the Drill Guide, locate the desired anteromedial tibial location for placement of the XT3 fixator. Mark location of the Half Pins positions using a skin marker. Position the Drill Guide such that the tibia and fibula are aligned using fluoroscopy; the Ø2mm Drill Bit for the intercalary Half Pins (3.0mm) must target the fibula.
   - 5.2. Make the skin incision medial to the planned location of the two intercalary Half Pins (3.0mm), centered between the outer Half Pins (5.0mm). Make dissection down to the bone for appropriate visualization of the target area.
   - 5.3. Retract the skin and place the Osteotomy Guide over the tibia. Using Ø2mm Drill Bits or K-wires, drill through the two center guide holes of the Osteotomy Guide through the fibula to prepare the pilot holes for the intercalary Ø3mm Half Pins and to provisionally secure the Osteotomy Guide to the bone.
     - Following the proximal and distal series of holes on the Osteotomy Guide, drill through each perimeter guide hole with a Ø2.4mm Steinmann Pin to define the margins of the osteotomy through the tibia .
     - Alternatively, a 0.4mm sawblade can be used to follow the proximal and distal slots in the Osteotomy Guide to prepare the intercalary segment.
   - 5.4. Slide the Drill Guide over the Osteotomy Guide. Using a Ø3.2mm Drill Bit, drill the remaining pilot holes for the Ø5mm Half Pins through Ø3.2mm Drill Sleeves placed in the outer fixation holes. Insert Ø5mm Half Pins through the pre-drilled holes. Alternatively, the self-drilling, self-tapping Ø5mm Half Pins can be inserted directly through the Drill Guide.
   - 5.5. Remove the Drill Guide and Osteotomy Guide.
   - 5.6. Slide the Drill Guide over the Ø5mm Half Pins. Insert the Ø3mm Half Pins through the Drill Guide and into the fibular intercalary segment. Confirm proper placement of all intercalary Ø3mm Half Pins using fluoroscopy.
   - 5.7. Close the skin and suture the incision wound. Confirm appropriate placement and bi-cortical fixation using fluoroscopy.
   - 5.8. Prior to installation of the XT3 fixator, insert the 3.5mm Hex Driver into the actuation screw and rotate clockwise (+ arrow) to confirm the actuation of the XT3 fixator. Rotate the actuation screw counter-clockwise (- arrow) to return the XT3 fixator to the original starting position. Slide the XT3 fixator over all the Ø5mm and Ø3mm Half Pins. Using the Drill Guide as a spacer, set the desired amount of soft tissue clearance between the bottom of the XT3 fixator and the skin. It is important to confirm equal spacing along the body of the XT3 to ensure the XT3 construct is both level and perpendicular to the Half Pins.
   - 5.9. Tighten all set screws in the XT3 fixator with the T20 Screwdriver to secure the XT3 locking set screws to each of the Half Pins. Lock the outer static Half Pins prior to locking the inner intercalary Half Pins
   - 5.10. To perform the ipsilateral transport, rotate the actuation screw clockwise (+ arrow) with the 3.5mm Hex Key.
   - 5.11. When usage of the device is complete, remove the XT3 fixator using the T20 Screwdriver to unlock all set screws in the XT3 fixator. Slide the XT3 fixator device off the Half Pins. Remove the Half Pins by counterclockwise rotation. Discard all components of the XT3 fixator and Half Pins according to hospital guidelines.

6. **Surgical Procedure – Soft Tissue Expansion**
   - 6.1. Using the Plate, locate the desired anteromedial tibial location for placement of the Plate and the XT3 fixator. Mark the locations of the Ø5mm Half Pins and Ø3mm Lift Pins using a skin marker.
   - 6.2. Make a proximal skin incision at the planned location of the first Ø5mm Half Pin. Perform dissection to the bone.
   - 6.3. Using a soft tissue elevator, elevate the soft tissue away from the anteromedial surface of the tibia and advance distally within the soft tissue to create a tunnel for the Plate. Insert the elevator to the depth indicated on the instrument to ensure adequate space for plate placement.
   - 6.4. Make stab incisions at the marked locations for the Ø3 mm Lift Pins. Drill unicortical decompression holes through the cortex.
   - 6.5. Assemble the Targeting Guide to the Plate by aligning the mating tab features and securing the guide in place with the Locking Bolt.
   - 6.6. Insert the Plate through the proximal incision and advance distally into the prepared soft tissue corridor. Position the construct such that the Targeting Guide barrel is centered within the incision site and the Plate is flush against the bone surface.
   - 6.7. Insert a Ø3.2 mm Drill Sleeve into the Locking Bolt. Using a Ø3.2 mm Drill Bit, drill a pilot hole through the proximal fixation hole to prepare for placement of the first Ø5 mm Half Pin. Remove the drill and sleeve and insert the Ø5 mm Half Pin through the Locking Bolt cannulation for bicortical fixation.
   - 6.8. Insert a Locking Bolt through the distal hole of the Targeting Guide. Place a Ø3.2 mm Drill Sleeve into the Locking Bolt and drill a pilot hole using the Ø3.2 mm Drill Bit. Remove the drill and sleeve and insert the second Ø5 mm Half Pin through the Locking Bolt cannulation for bicortical fixation.
   - 6.9. Insert two Ø3 mm Lift Pins through the Targeting Guide and thread them into the corresponding Plate locking holes to secure the Plate.
   - 6.10. Remove the Targeting Guide by unthreading the Locking Bolt from the Plate and sliding the guide off the Ø5 mm Half Pins.
   - 6.11. Proceed with the closure of the subcutaneous tissue and skin incisions.
   - 6.12. Prior to installation of the XT3 fixator, insert the 3.5mm Hex Driver into the actuation screw and rotate clockwise (+ arrow) to confirm the actuation of the XT3 fixator. Rotate the actuation screw counter-clockwise (- arrow) to return the XT3 fixator to the original starting position. Slide the XT3 fixator over all the Ø5mm and Ø3mm Half Pins. Using the Targeting Guide as a spacer, set the desired amount of soft tissue clearance between the bottom of the XT3 fixator and the skin. It is important to confirm equal spacing along the body of the XT3 to ensure the XT3 construct is both level and perpendicular to the Half Pins.
   - 6.13. Tighten all set screws in the XT3 fixator with the T20 Screwdriver to secure the XT3 locking set screws to each of

the Half Pins. Lock the outer static Half Pins prior to locking the inner intercalary Half Pins

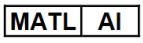
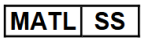
6.14. To perform the soft tissue expansion, rotate the actuation screw clockwise (+ arrow) with the 3.5mm Hex Key to distract the intercalary segment. Rotate the actuation screw counter-clockwise (- arrow) with the 3.5mm Hex Key to retract the intercalary segment.

6.15. When usage of the device is complete, remove the XT3 fixator using the T20 Screwdriver to unlock all set screws in the XT3 fixator. Slide the XT3 fixator device off the Half Pins. Using a Universal Chuck, remove the Half Pins by counterclockwise rotation. Discard all components of the XT3 fixator and Half Pins according to hospital guidelines.

7. Storage, Handling, and Disposal

The Biodynamik XT3 System should be stored, handled, and disposed of per hospital guidelines.

8. Symbols Definition

Symbol	Definition
	Model Number
	Quantity
	Lot Number
	Consult instructions for use
	Non-sterile
	Do not use if package is damaged
	Do not reuse
	Manufacturer
	Prescription use only
	Medical Device
	Unique Device Identifier
	Sterilized by Gamma Irradiation
	Use By Date
	Do Not Resterilize
	Material: Aluminum Alloy
	Material: Stainless Steel, various grades

Biodynamik, Inc.
11 Orchard Rd, Suite 107
Lake Forest, CA 92630 USA
Customer Service: +1 949-235-5351
www.biodynamik.com