intraFIX

INSTRUCTIONS FOR USE PAMPHLET

IntrMED
Rhodes Research Center
Clemson University
Clemson, SC 29632

TABLE OF CONTENTS

INSTRUCTIONS FOR USE

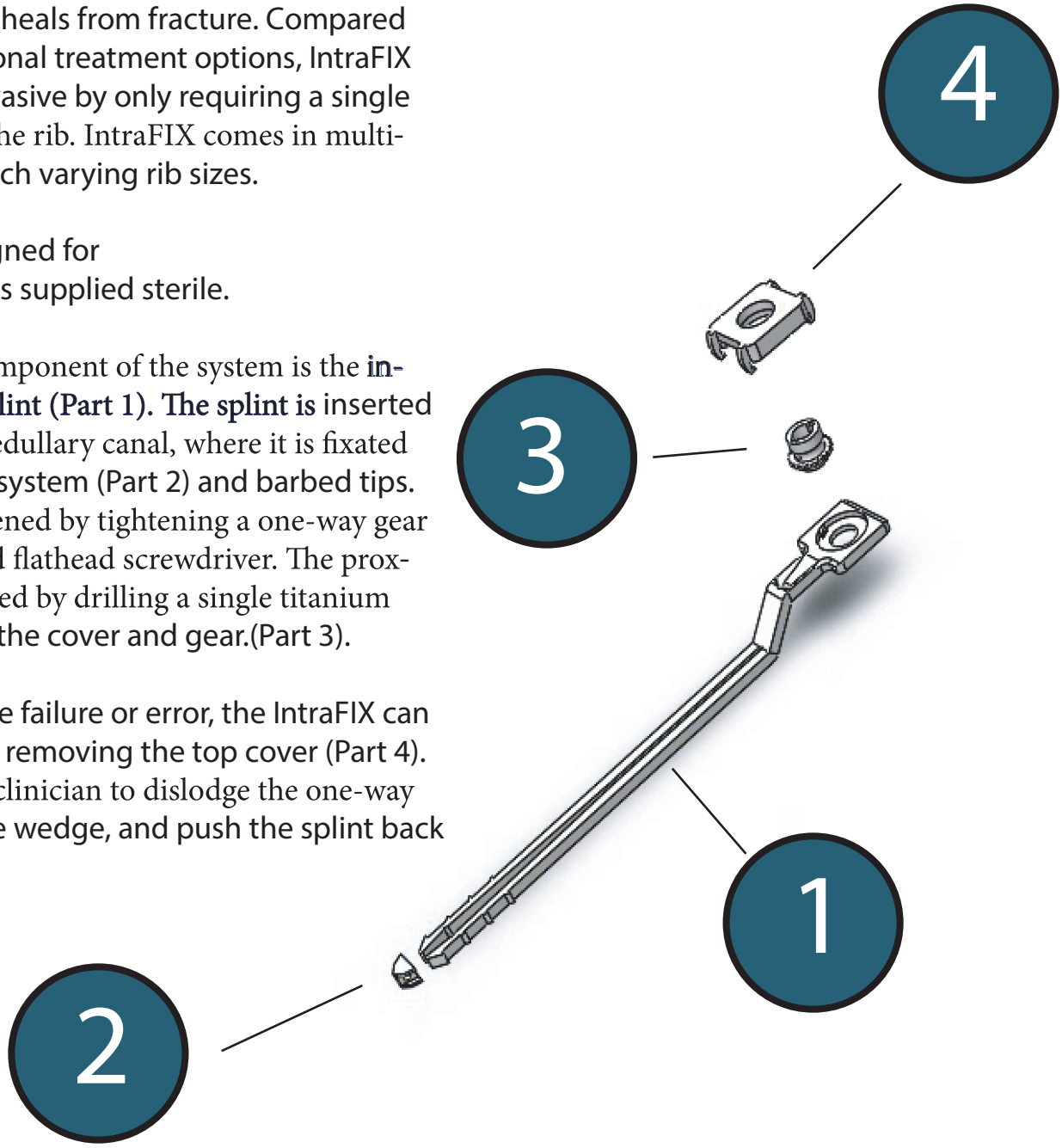
DEVICE DESCRIPTION

IntraFIX is a novel intramedullary splint used to treat rib fractue injuries. The system consists of three splint systems, which includes a top cover, titanium wire, and titanium screw. The IntraFIX provides proximal and distal fixation to stabilize the rib as it heals from fracture. Compared to other traditional treatment options, IntraFIX is minimally invasive by only requiring a single screw to fixate the rib. IntraFIX comes in multiple sizes to match varying rib sizes.

IntraFIX is designed for
single use and is supplied sterile.

The primary component of the system is the **intramedullary splint (Part 1). The splint is** inserted into the intramedullary canal, where it is fixated using a wedge system (Part 2) and barbed tips. The splint is opened by tightening a one-way gear using a standard flathead screwdriver. The proximal end is fixated by drilling a single titanium screw through the cover and gear.(Part 3).

In case of device failure or error, the IntraFIX can be retracted by removing the top cover (Part 4). This allows the clinician to dislodge the one-way gear, loosen the wedge, and push the splint back together.



INSTRUCTIONS FOR USE

CONTENTS

3 IntraFIX Intramedullary Splints Systems comprising of:

- 1ea. Splint
- 1ea. Screw
- 1ea. Top Cover
- 1ea. Titanium Wire

INDICATIONS FOR USE

The IntraMED IntraFIX Intramedullary Splint is indicated for use in skeletally mature patients with normal, non-osteoporotic bone for chest wall fixation, where:

The IntraMED IntraFIX Intramedullary Splint is indicated for the fixation and stabilization of ribs.

CONTRAINDICATIONS

The IntraMED IntraFIX Intramedullary Splint is contraindicated for:

- The fixation of the sternum in acute cardiac patients, due to the potential delay if emergent re-entry is required.
- Screw attachment or fixation to the clavicle or spine.
- Use in patients with latent or active infection, with sepsis, or who are unwilling or incapable of following postoperative care instructions.
- Use in patients with osteoporotic or poor bone quality.

INSTRUCTIONS FOR USE

PRECAUTIONS

Do not re-use this device. Products intended for single-use must not be re-used. The re-use or reprocessing of this device may compromise the structural integrity and lead to device failure which may led to patient injury, illness, or death.

- Inspect device prior to use. Discard device if device is damaged.
- This device can break intraoperatively if exposed to excessive forces or outside the recommended surgical technique.
- Do not deploy the device past the instructed distance. Excessive deployment may cause device failure or harm to the patient.
- Post-operative care must be determined by the clinician.
- Avoid significant muscle division to preserve as much respiratory function as possible.
- Avoid any steep angle during splint insertion to prevent any additional injuries to the rib, spine, or underlying organs.

⚠ WARNINGS

Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is damaged.

- Read instructions for use completely prior to use.
- It is the responsibility of the surgeon to be familiar with the appropriate surgical techniques before using this device.
- Insufficient deployment may result in inadequate fixation and prolonged bone healing.
- The efficacy of this device in other applications has not been established.
- Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those place on normal healthy bones.

ADVERSE REACTIONS

Device specific adverse reactions include but are not limited to:

- Splint breakage
- Wire breakage
- Loss of fixation of screw and splint
- Loss of chest wall stability
- Foreign body reaction
- Infection
- Allergic reaction
- Inflammatory reaction
- Seroma

STERILIZATION

Sterilized using irradiation.

The device provided is sterile until the packaging is open or has been damaged. Do not resterilize.

MATERIAL SPECIFICATIONS

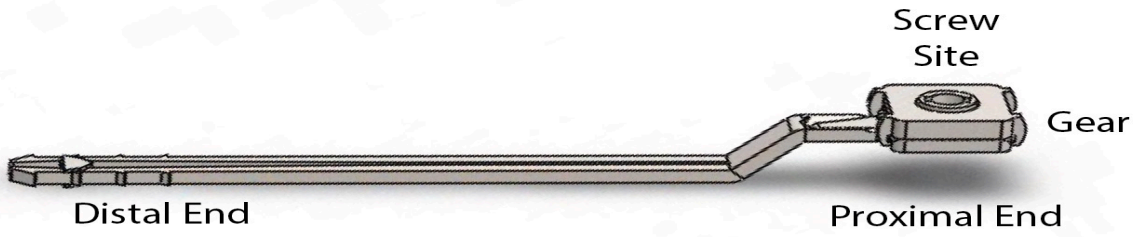
- Splint: Titanium 6Al4V
- Top Cover: Titanium 6Al4V
- Screw: Titanium 6Al4V
- Wire: Titanium 6Al4V

STORAGE CONDITIONS

This device should be stored in the original packaging at room temperature. The package should be kept away from moisture and not be opened until immediately before use.

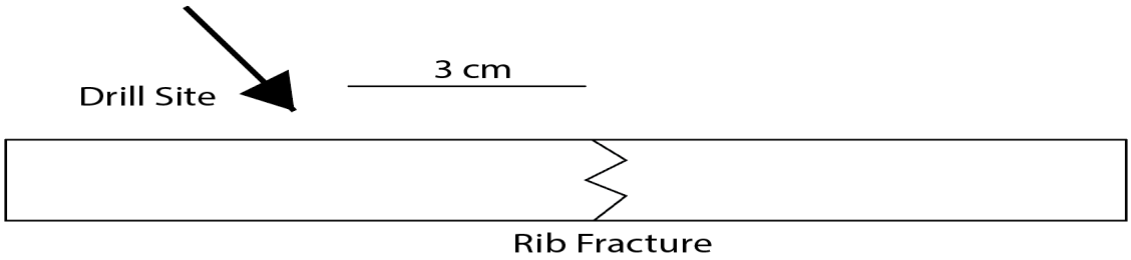
Before use, check the expiration date and verify the integrity of the sterile packaging. Do not use if package is damaged.

INSTRUCTIONS FOR USE



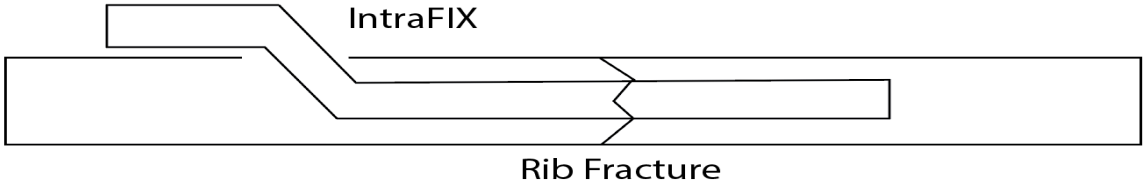
1. Make an appropriate incision to expose the rib fracture. Determine size of IntraFIX needed for fixation.

2. Drill a pilot hole 3 cm from the fracture site. Next, drill a hole using a 2.5mm drill bit at a 45-degree angle at the same location as the pilot hole. The angle should be pointed towards the fracture.



3. Locate fracture and set. Use forceps to align the fracture.

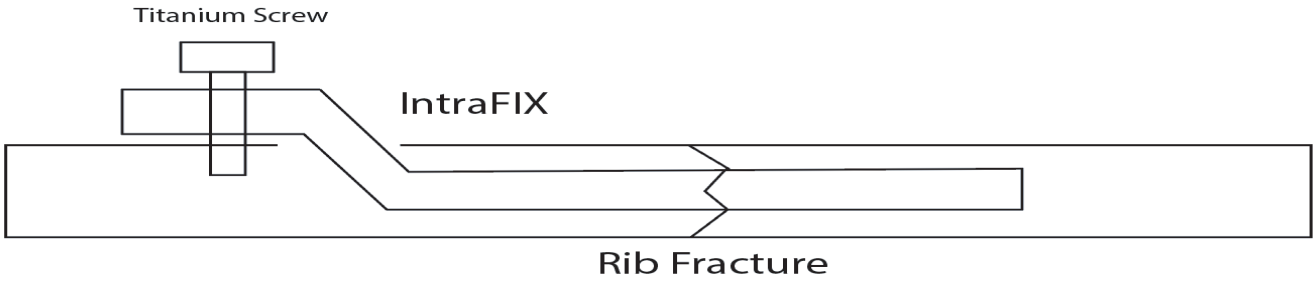
4. Insert IntraFIX through the drill hole until the top of the device is flushed to the side of the bone.



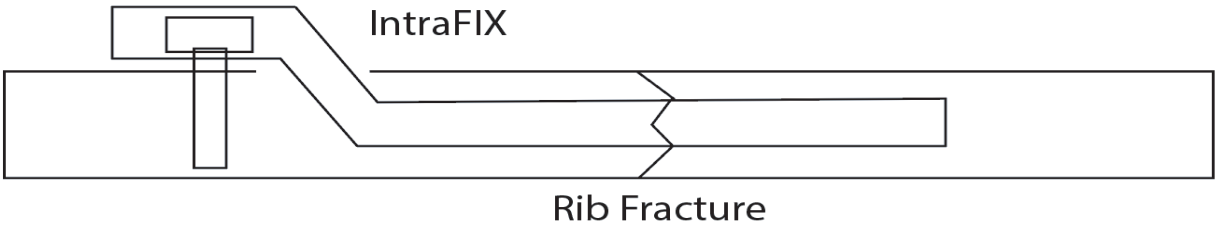
INSTRUCTIONS FOR USE

5. Using a screwdriver, turn the one-way gear clockwise to pull the wedge towards the proximal end, opening the splint. Screw-until the surgeon is certain the device is secured within the rib.

6. Insert titanium screw at a 90-degree angle through the proximal end of the IntraFIX. Tighten with screwdriver to fixate the device to the side of the rib.



7. Check to ensure the device is properly fixated.



8. Close incision.

intra MED

For any additional information on the IntraFIX Intramedullary Splint and its use, contact IntraMED:

Phone: (864)612-9563
Email: intramed@clemson.edu

CLEMSON BIOENGINEERING

PRISMA HEALTH

IntraMED
Rhodes Research Center, Clemson University
Clemson, SC 29632

Manufactured in Leuven, Belgium

℞ ONLY