

# External Fixation with Automated Strut Adjustment

MAXFRAME AUTOSTRUT™

ICD-10 Coordination and  
Maintenance Committee Meeting

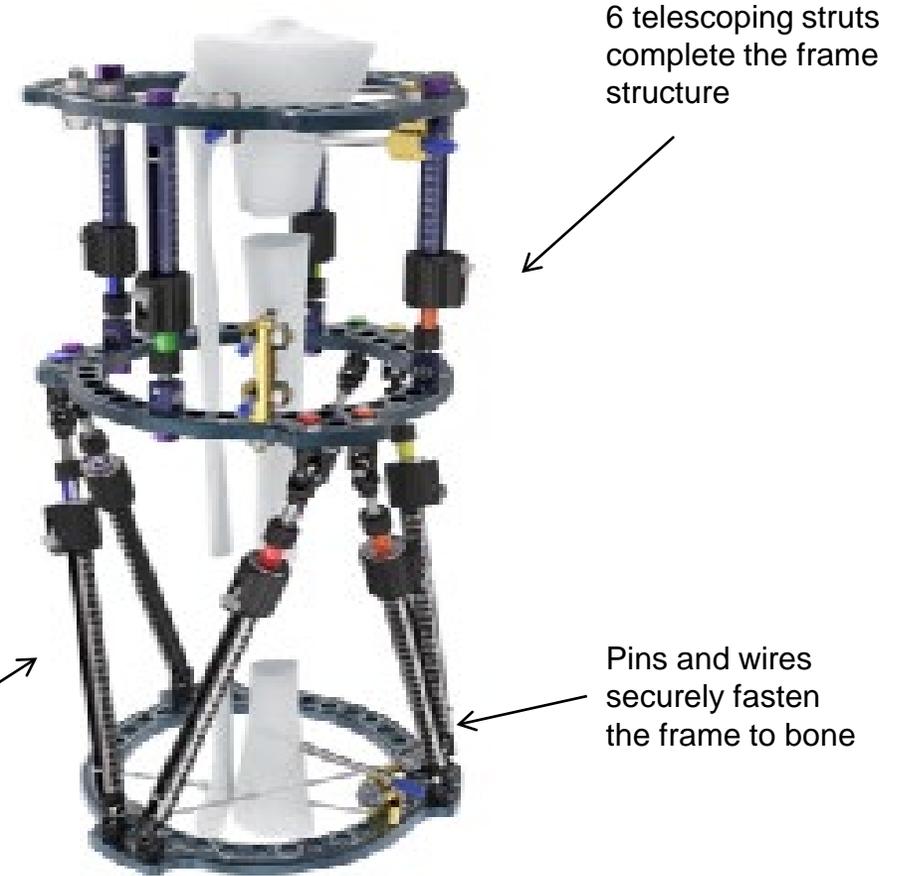
J. Spence Reid, MD

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# External Fixation for Distraction Using Hexapod Ring Fixation (HRF)

- Hexapod ring fixation systems are a class of external fixation systems that are used to address a range of conditions, including deformity correction, limb lengthening and fracture fixation for the femur, tibia, humerus, radius or ulna. <sup>1</sup>
- Utilizes a circular frame attached to the appendicular skeleton with pins and wires, along with telescoping struts that allow adjustment of the ring and bone segment position. <sup>2 3</sup>



6 telescoping struts complete the frame structure

Pins and wires securely fasten the frame to bone

External fixation system forms circular frame around affected limb

MAXFRAME™ SYSTEM

1. Reid JS, Vanderkarr M, Ray B, Chitnis A, Holy CE, Sparks C. Two year clinical and economic burden, risk and outcomes following application of software-assisted hexapod ring fixation systems. BMC Musculoskelet Disord. 2022;23(1):25. 2. Reid JS, Vanderkarr M, Ray B, Chitnis A, Holy CE, Sparks C. Hospitalization for computer-assisted hexapod ring fixation application - analyses of patient variability, peri-operative complications, hospital costs, and discharge status. BMC Musculoskelet Disord. 2022;23(1):211. 3. Fragomen AT, Rozbruch SR. The mechanics of external fixation. HSS journal : the musculoskeletal journal of Hospital for Special Surgery. 2007;3(1):13-29.

# Manual Hexapod Ring Fixation Surgical and Post-operative Treatment Overview

## Surgical Process



MAXFRAME™ device and **manual struts** are placed on patient's affected limb by the surgeon, with the goal of correcting the deformity gradually over time.

## Post-surgical Process

MAXFRAME  
MAX Ankle Correction System

DePuySynthes

**Strut Adjustment Instructions**

Patient name: Johnson, Max  
Patient contact info: J  
Screen name: White, Carol  
Surgeon contact info: Carole.John@rotemmail.com / (855)200-4550  
Case: Bone deformity Tibia Left 3  
Treatment: Tibia Left Fracture  
Approved: 3/6/2021 11:13:20 AM

Date	Day	Red Strut 1	Orange Strut 2	Yellow Strut 3	Green Strut 4	Blue Strut 5	Purple Strut 6
3/14/2021	Sunday	1	210	204	207	206	204
3/15/2021	Monday	2	211	205	206	204	207
3/16/2021	Tuesday	3	211	206	204	202	206
3/17/2021	Wednesday	4	212	206	202	200	204
3/18/2021	Thursday	5	212	207	200	198	202
3/19/2021	Friday	6	212	208	200	199	200
3/20/2021	Saturday	7	213	208	207	204	200
3/21/2021	Sunday	8	214	209	205	201	201
3/22/2021	Monday	9	215	210	203	200	201
3/23/2021	Tuesday	10	215	210	201	207	202
3/24/2021	Wednesday	11	216	211	200	205	200
3/25/2021	Thursday	12	216	211	207	200	204
3/26/2021	Friday	13	217	212	205	201	200
3/27/2021	Saturday	14	217	212	202	200	204
3/28/2021	Sunday	15	218	213	200	207	204
3/29/2021	Monday	16	218	213	205	200	207
3/30/2021	Tuesday	17	219	214	200	203	207
3/31/2021	Wednesday	18	219	214	204	201	200
4/1/2021	Thursday	19	220	215	201	200	203

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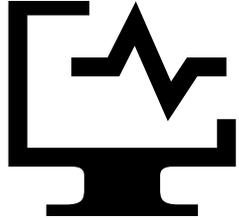


Patient is provided with a **manual strut adjustment treatment plan** specific to their recovery.

Patient is discharged and **directed to make manual strut adjustments** according to treatment plan for a defined period of time.

The frame is removed when the patient's treatment plan is complete, and deformity correction has been achieved.

# Complexities of Manual Hexapod Ring Fixation



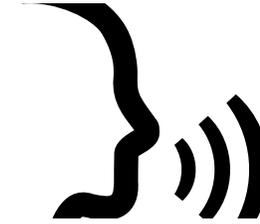
## Treatment Plan Generation

Surgeons utilize complex, computer software enabled treatment plans to guide the adjustment process.



## Paper-based Instructions

Surgeons print out the treatment plan on paper and provide it to the patient.



## Patient Education

Clinicians educate the patient and caregiver on how to read and follow the treatment plan.



## Manual Strut Adjustments

Patients or caregivers manually turn each strut several times a day to meet the prescribed schedule and achieve the desired direction and measurement for months following surgery

# MAXFRAME AUTOSTRUT™

By **automating** the strut-adjustment process and generating more-frequent micro adjustments, MAXFRAME AUTOSTRUT™ system is a solution for more **efficient management of the intended applications** that mitigate patient user-error.



## Indications

MAXFRAME AUTOSTRUT™ is indicated for adults, children (3–12) and adolescents (12–21) in which growth plates have fused or will not be crossed with hardware:

- Fracture fixation (open and closed)
- Pseudoarthrosis of long bones
- Limb lengthening (epiphyseal or metaphyseal distraction)
- Joint arthrodesis
- Infected fractures or nonunion
- Correction of bony or soft tissue deformities
- Correction of segmental defects

# Hardware and Software Components of MAXFRAME AUTOSTRUT™

The MAXFRAME AUTOSTRUT™ technology integrates into the existing MAXFRAME™ system.

## FDA Approved MAXFRAME™ System

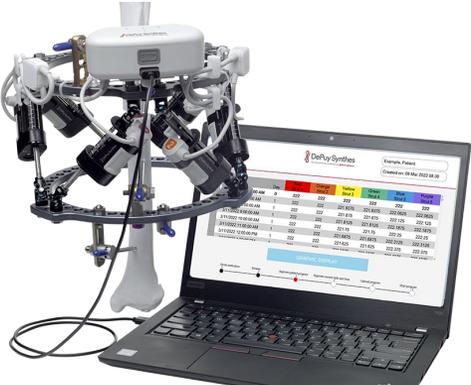


## FDA Approved **automated struts** and Control System work with the existing MAXFRAME™ Device

MAXFRAME™ hardware and software allowing physicians to download the manual treatment plan to the device, chart patient progress and, if required, adjust the treatment plan and schedule

**Automated struts** replace the struts in the existing MAXFRAME™ system

Automated Hexapod Control System Kit consisting of control unit with a wired connection to six motorized struts

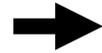


# Procedural Steps for MAXFRAME AUTOSTRUT™

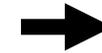
## Surgical Process

Surgeon addresses the bone defect (e.g., reduces fracture, performs osteotomy) and then inserts pins into the patient's bone segments

Surgeon assembles the MAXFRAME™ multi-axial ring fixation frame on the patient in the operating room



Surgeon attaches **automated struts** to MAXFRAME™ rings in the operating room



## Post-surgical Process

The MAXFRAME AUTOSTRUT™ control box ring interface, motors, and cables are attached to the MAXFRAME™

Control system is activated in the clinic (or outside of the sterile field) by attaching a computer running MAXFRAME AUTOSTRUT™ Software to the main control box via a USB cable

The provider uploads patient specific strut adjustment plan to the MAXFRAME AUTOSTRUT™ Control System

**Treatment plan is automatically implemented** for a specific amount of time after patient is discharged

The multi-axial ring fixation frame and control system are removed once the patient's treatment plan is complete

# Medical Record Documentation

Documentation of the use of the MAXFRAME AUTOSTRUT™ technology can be found in the operating room (O.R.) report or surgical notes

Terms related to MAXFRAME AUTOSTRUT™ include:

- Automated struts
- MAXFRAME AUTOSTRUT™
- External fixation with Maxframe automated struts
- Hexapod ring fixation with Maxframe automated struts
- Hexapod circular external fixators with Maxframe automated struts

# Questions?