

External Fixation with Automated Strut Adjustment

MAXFRAME AUTOSTRUT™

ICD-10 Coordination and
Maintenance Committee Meeting

J. Spence Reid, MD

September 2024

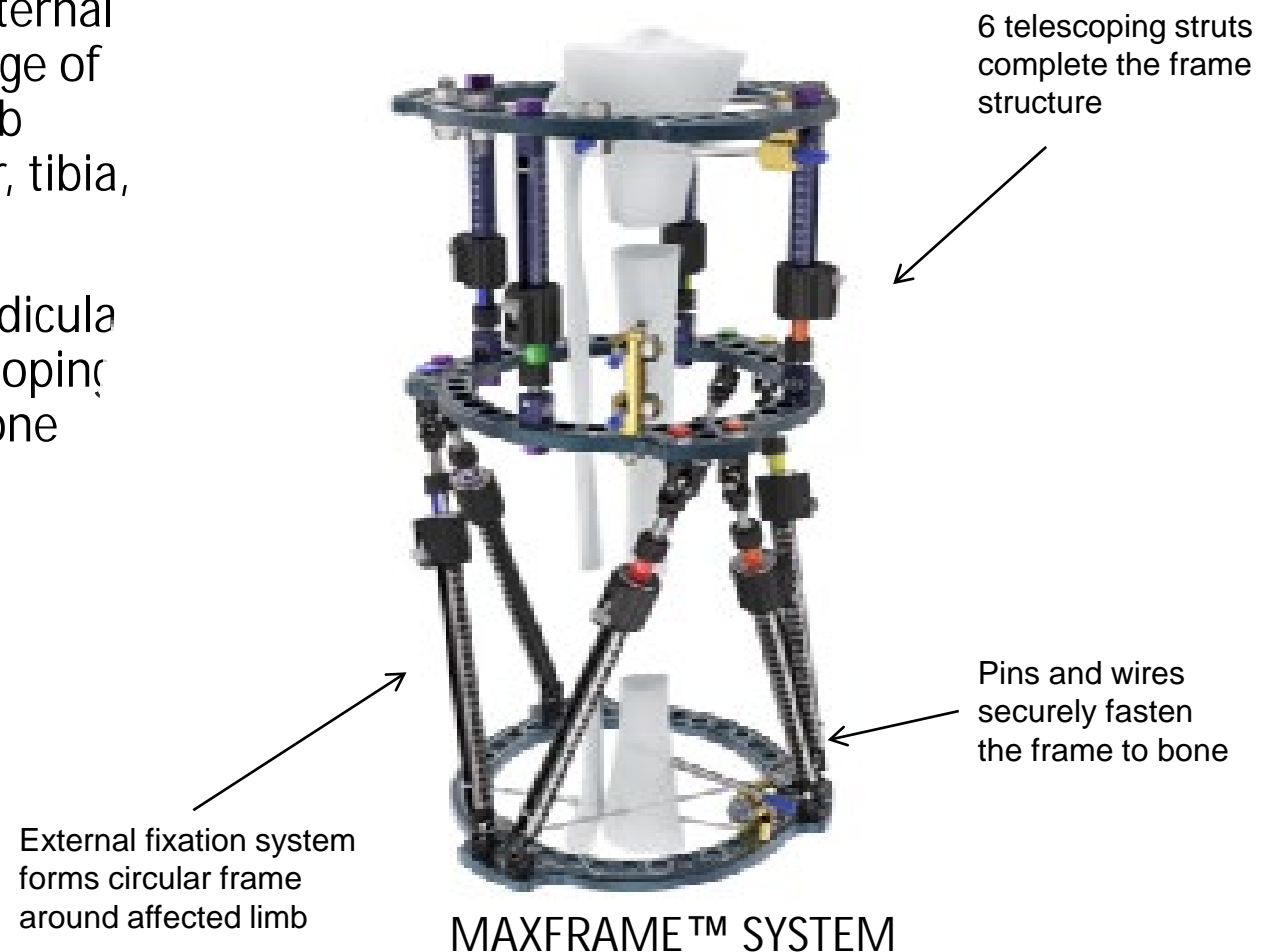
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| Innovation



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. ¹
- 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. ^{2 3}



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-Actix Correction System

DePuySynthes

Strut Adjustment Instructions

Patient name: Johnson, Max
Patient contact info: /
Surgeon name: White, Carol
Surgeon contact info: Carole.John.White@protonmail.com / (555)200-4550
Case: Bone deformity Tibia Left 3
Treatment: Tibia Left Fracture
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Date	Day	Strut 1	Strut 2	Strut 3	Strut 4	Strut 5	Strut 6
3/14/2021	Sunday	1	210	204	207	209	204
3/15/2021	Monday	2	211	205	206	204	207
3/16/2021	Tuesday	3	211	206	204	202	205
3/17/2021	Wednesday	4	212	206	202	200	204
3/18/2021	Thursday	5	212	207	200	200	202
3/19/2021	Friday	6	213	208	210	200	200
3/20/2021	Saturday	7	213	208	211	204	210
3/21/2021	Sunday	8	214	209	210	201	211
3/22/2021	Monday	9	215	210	213	210	211
3/23/2021	Tuesday	10	215	210	211	211	212
3/24/2021	Wednesday	11	216	211	209	210	213
3/25/2021	Thursday	12	216	211	207	210	214
3/26/2021	Friday	13	217	212	205	211	214
3/27/2021	Saturday	14	217	212	202	200	215
3/28/2021	Sunday	15	218	213	200	201	216
3/29/2021	Monday	16	218	213	200	200	217
3/30/2021	Tuesday	17	219	214	200	201	217
3/31/2021	Wednesday	18	219	214	204	201	218
4/1/2021	Thursday	19	220	215	201	200	218

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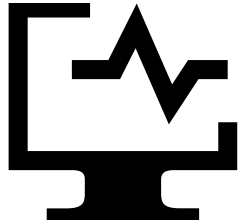


Patient is provided with a **manual strut adjustment treatment plan** specific to their recovery.

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

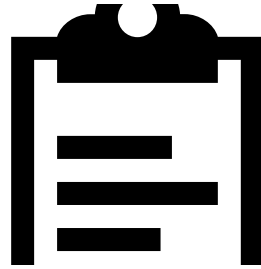
The frame is removed when the patient's treatment plan is complete, and deformity correction has been achieved.

Complexities of Manual Hexapod Ring Fixation



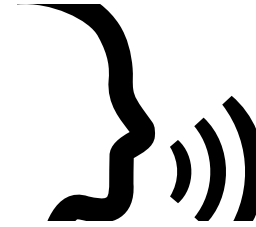
Treatment Plan Generation

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



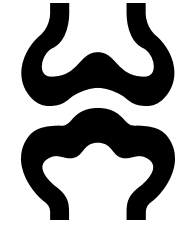
Paper-based Instructions

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

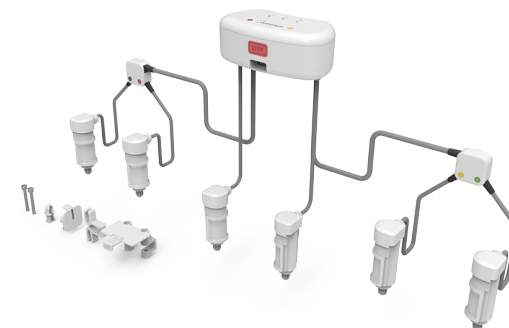
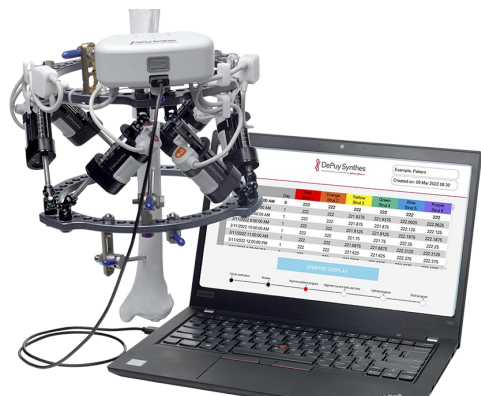


FDA Approved **automated struts** and Control System work with the existing MAXFRAME™ Device

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?