Instructions for Use
External Fixation and Distraction Systems

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

EC REP

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

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Instructions for Use

External Fixation and Distraction Systems

Devices in scope:

Instruments:

Article No.
03.312.001
392.903
392.907
392.911
392.913
03.311.008

Implants:

Nail for Pelvic C-Clamp, cannulated, Stainless Steel

Article No.	Length (mm)
02.306.006	190
02.306.007	210

Steinmann Pin, Stainless Steel

Article No.	∅ (mm)	Length (mm)
293.000.302	3.0	150
293.000.352	3.5	200

Steinmann Pin with trocar tip, Stainless Steel

Article No.	Article No. (sterile packed)	∅ (mm)	Length (mm)
293.350	293.350S	3.5	125
293.360	293.360S	3.5	150
293.400	293.400S	4.0	150
293.410	293.410S	4.0	175
293.420	293.420S	4.0	200
293.440	293.440S	4.5	125
293.450	293.450S	4.5	150
293.460	293.460S	4.5	175
293.470	293.470S	4.5	200
293.480	293.480S	4.5	250
293.490	293.490S	4.5	225
293.500	293.500S	5.0	150
293.510	293.510S	5.0	175
293.520	293.520S	5.0	200
293.530	293.530S	5.0	250
293.540	293.540S	5.0	300
293.580	293.580S	5.0	225
293.590	293.590S	5.0	275

Steinmann Pin with trocar tip, Ti-6Al-7Nb (TAN)

Article No.	Article No. (sterile packed)	∅ (mm)	Length (mm)
493.350	493.350S	3.5	125
493.360	493.360S	3.5	150
493.400	493.400S	4.0	150
493.410	493.410S	4.0	175
493.420	493.420S	4.0	200
493.440	493.440S	4.5	125
493.450	493.450S	4.5	150
493.460	493.460S	4.5	175
493.470	493.470S	4.5	200
493.480	493.480S	4.5	250
493.490	493.490S	4.5	225
493.500	493.500S	5.0	150
493.510	493.510S	5.0	175
493.520	493.520S	5.0	200
493.530	493.530S	5.0	250
493.540	493.540S	5.0	300
493.580	493.580S	5.0	225
493.590	493.590S	5.0	275

Steinmann Pin with middle thread, Stainless Steel

Article No.	Article No. (sterile packed)	∅ (mm)	Length (mm)
293.640		5.0	150
293.680	293.680S	4.5	175
293.690	293.690S	5.0	175
293.730	293.730S	4.5	200
293.740	293.740S	5.0	200
293.790		5.0	225
293.840		5.0	250
293.890	293.890S	5.0	275
293.940	293.940S	5.0	300

Steinmann Pin with middle thread, Ti-6Al-4V (TAV) or Ti-6Al-4V ELI (TAV)

Article No.	Article No. (sterile packed)	∅ (mm)	Length (mm)
493.740	493.740S	5.0	200
493.840	493.840S	5.0	250

Steinmann Pin with drill tip, Stainless Steel

Article No.	Article No. (sterile packed)	∅ (mm)	Length (mm)
293.130	293.130S	4.5	150
293.140	293.140S	4.5	175
293.150	293.150S	4.5	200
293.220	293.220S	5.0	125
293.230	293.230S	5.0	150
293.240	293.240S	5.0	175
293.250	293.250S	5.0	200
293.260	293.260S	5.0	225
293.270	293.270S	5.0	250
293.280	293.280S	5.0	275
293.290	293.290S	5.0	300

Schanz Screw, Stainless Steel

Article No.	∅ (mm)	Total length (mm)	Thread length (mm)
294.000.425	4.0/2.7*	50	10
294.000.426	4.0/2.7*	60	10
294.000.453	4.5/3.5*	90	10
294.000.454	4.5/3.5*	90	25

Self-tapping Schanz Screw, Stainless Steel

Article No.	Article No. (sterile packed)	∅ (mm)	Total length (mm)	Thread length (mm)
294.300	294.300S	4.0/3.0*	80	20
294.430	294.430S	4.0	60	25
294.440	294.440S	4.0	80	25
294.445	294.445S	4.0/2.5*	80	20
294.450	294.450S	4.0	100	25
294.460	294.460S	4.0	125	25
294.520	294.520S	5.0	100	50
294.530	294.530S	5.0	125	50
294.540	294.540S	5.0	150	50
294.550	294.550S	5.0	175	50
294.560	294.560S	5.0	200	50
294.570	294.570S	5.0	250	50
294.650	294.650S	6.0	100	50
294.660	294.660S	6.0	130	50
294.670	294.670S	6.0	160	50
294.680	294.680S	6.0	190	50

Self-tapping Schanz Screw, Ti-6Al-7Nb (TAN)

Article No.	Article No. (sterile packed)	∅ (mm)	Total length (mm)	Thread length (mm)
494.300	494.300S	4.0/3.0*	80	20
494.430	494.430S	4.0	60	25
494.440	494.440S	4.0	80	25
494.445	494.445S	4.0/2.5*	80	20
494.450	494.450S	4.0	100	25
494.460	494.460S	4.0	125	25
494.520	494.520S	5.0	100	50
494.530	494.530S	5.0	125	50
494.540	494.540S	5.0	150	50
494.550	494.550S	5.0	175	50
494.560	494.560S	5.0	200	50
494.570	494.570S	5.0	250	50
494.650	494.650S	5.0	100	50
494.660	494.660S	6.0	130	50
494.670	494.670S	6.0	160	50
494.680	494.680S	6.0	190	50

Self-drilling Schanz Screw, Commercially Pure Titanium (TiCP), Hydroxyapatite (HA) coating, sterile

Article No.	∅ (mm)	Length (mm)
494.784SHA	5.0	150
494.785SHA	5.0	175
494.786SHA	5.0	200

Self-drilling Schanz Screw, Stainless Steel, Hydroxyapatite (HA) coating, sterile

Article No.	∅ (mm)	Length (mm)
294.776SHA	4.0	100
294.777SHA	4.0	125
294.778SHA	4.0	150
294.779SHA	4.0	175
294.782SHA	5.0	100
294.783SHA	5.0	125
294.784SHA	5.0	150
294.785SHA	5.0	175
294.786SHA	5.0	200
294.788SHA	5.0	250
294.792SHA	6.0	100
294.793SHA	6.0	125
294.794SHA	6.0	150
294.795SHA	6.0	175
294.796SHA	6.0	200
294.798SHA	6.0	250

Schanz Screw with spade point tip, Stainless Steel, Hydroxyapatite (HA) coating, sterile

Article No.	∅ (mm)	Length (mm)
294.450SHA	4.0	100
294.460SHA	4.0	120
294.520SHA	5.0	100
294.530SHA	5.0	125
294.540SHA	5.0	150
294.550SHA	5.0	170
294.560SHA	5.0	200
294.570SHA	5.0	250
294.670SHA	6.0	160
294.680SHA	6.0	190
294.730SHA	4.5	125
294.740SHA	4.5	150
294.750SHA	4.5	175
294.760SHA	4.5	200

Seldrill™ Schanz Screw, Stainless Steel

Article No.	Article No. (sterile packed)	∅ (mm)	Total length (mm)	Thread length (mm)
294.769	294.769S	4.0/2.5*	80	20
294.771	294.771S	4.0/3.0*	80	20
294.772	294.772S	4.0/3.0*	100	20
294.774	294.774S	4.0	60	20
294.775	294.775S	4.0	80	20
294.776	294.776S	4.0	100	30
294.777	294.777S	4.0	125	40
294.778	294.778S	4.0	150	40
294.779	294.779S	4.0	175	40
294.782	294.782S	5.0	100	30
294.783	294.783S	5.0	125	40
294.784	294.784S	5.0	150	60
294.785	294.785S	5.0	175	60
294.786	294.786S	5.0	200	80
294.788	294.788S	5.0	250	80
294.792	294.792S	6.0	100	30
294.793	294.793S	6.0	125	40
294.794	294.794S	6.0	150	60
294.795	294.795S	6.0	175	60
294.796	294.796S	6.0	200	80
294.798	294.798S	6.0	250	80

Seldrill™ Schanz Screw, Commercially Pure Titanium (TiCP)

Article No.	Article No. (sterile packed)	∅ (mm)	Total length (mm)	Thread length (mm)
494.769	494.769S	4.0/2.5*	80	20
494.771	494.771S	4.0/3.0*	80	20
494.772	494.772S	4.0/3.0*	100	20
494.774	494.774S	4.0	60	20
494.775	494.775S	4.0	80	20
494.776	494.776S	4.0	100	30
494.777	494.777S	4.0	125	40
494.778	494.778S	4.0	150	40
494.779	494.779S	4.0	175	40
494.782	494.782S	5.0	100	30
494.783	494.783S	5.0	125	40
494.784	494.784S	5.0	150	60
494.785	494.785S	5.0	175	60
494.786	494.786S	5.0	200	80
494.788	494.788S	5.0	250	80
494.792	494.792S	6.0	100	30
494.793	494.793S	6.0	125	40
494.794	494.794S	6.0	150	60
494.795	494.795S	6.0	175	60
494.796	494.796S	6.0	200	80
494.798	494.798S	6.0	250	80

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

* Shaft/thread diameter. Shaft and thread diameters are the same for all other sizes.

Introduction
Associated device systems with these instructions for use are:
– Elbow Hinge Fixator
– External Distal Radius Fixator
– Hybrid Ring Fixator
– Large and Medium-Size External Fixators
– MEFiSTO
– Pelvic C-Clamp
– Schanz Screws and Steinmann Pins
– Segment Transport MEFiSTO
– Small External Fixator
– MAXFRAME –Multi-Axial Correction System
– The Distraction Osteogenesis Ring System
– Large Distractor – Tibia

Synthes External Fixation and Distraction Systems consists of various implants including Schanz Screws (self-tapping, self-drilling and HA-coated), Steinmann Pins, and Pelvic C-Clamp Cannulated Nails. Schanz Screws and Steinmann Pins can be used in various anatomical locations in the body based on the external fixation and distraction system being utilized. The Pelvic C-Clamp Cannulated Nails are only used in the pelvic ring.

All external fixator implants are single packed. Schanz screws and Steinmann pins are sold sterile and/or non-sterile, while the nails for pelvic C-clamp are only sold non-sterile.

The external fixator instruments listed are reusable and are sold non-sterile.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Devices(s)	Material(s)	Standard(s)
Steinmann Pin	Stainless Steel 316L	ISO 5832-1 and ASTM F138
	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
	Ti-6Al-4V (TAV) Titanium Alloy	ISO 5832-3
	Ti-6Al-4V ELI (TAV) Titanium Alloy	ASTM F136
Schanz Screw	Stainless Steel 316L	ISO 5832-1 and ASTM F138
	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
	Ti Grade 4 (CP4) also referred as to Commercially Pure Titanium (TiCP)	ISO 5832-2 Gr 4A, 4B
	Hydroxyapatite (HA)	ASTM F1185
Nail f/Pelvic C-Clamp	Stainless Steel 316L	ISO 5832-1 and ASTM F138
	Stainless Steel 301	ISO 7153-1
	PA-66 white	NONE
	Viton	NONE

Intended Use

External Fixator Devices
External Fixator Devices are intended for temporary fixation and intra- and postoperative treatment of open and closed fractures and elective orthopedic interventions.

Maxframe
The DePuy Synthes MAXFRAME Multi-Axial Correction System is intended for external fixation of fractured long bones and bones of the foot, limb lengthening, and deformity correction in adult, children* (3–12), and adolescent* (12–21) patient populations. The DePuy Synthes MAXFRAME Multi-Axial Correction System utilizes software for assisting surgeons in treatment planning.

* in which the growth plates have fused or will not be crossed."

Large Distractor- Tibia
The Large Distractor aids in fracture reduction and holds provisional stabilization prior to definitive fixation such as:
– Distraction
– Rotation
– Valgus-varus
– Anterior-posterior
– Compression

Indications
Please refer to the table at the end of this IFU.

Contraindications
Please refer to the table at the end of this IFU.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in orthopedic surgery, are aware of general risks of orthopedic surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in orthopedic surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
Expected clinical benefits of external fixation and distraction devices such as
– Elbow Hinge Fixator
– External Distal Radius Fixator
– Hybrid Ring Fixator
– Large and Medium-Size External Fixators
– MEFiSTO
– Pelvic C-Clamp
– Schanz Screws and Steinmann Pins
– Segment Transport MEFiSTO
– Small External Fixator
– MAXFRAME –Multi-Axial Correction System
– The Distraction Osteogenesis Ring System
– Large Distractor – Tibia
when used according to instructions for use and recommended technique are,
– Stabilize bone segment and facilitate healing
– Restore anatomical relationship and function
– Provide minimally invasive technique
– Allow adjustments postoperatively.

A summary of safety and clinical performance can be found at the following link: http://ec.europa.eu/tools/eudamed

Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched.

Performance Characteristics of the Device
Synthes has established the performance and safety of External fixation and distraction systems, and that they represent state of the art medical devices for distraction, temporary fixation and intra- and post-operative treatment of open and closed fractures and for elective orthopedic interventions when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
– Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction
– Infection
– Poor Joint Mechanics
– Damage to Surrounding Structures
– Damage to Vital Organs
– Malunion/Non-union
– Neuro-vascular Damage
– Pain or Discomfort
– Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis
– Soft Tissue Damage (including Compartment Syndrome)
– Injury to User
– Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective Synthes implant instructions for use.

Sterile Device

Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.


Do not resterilize

Re-sterilization of Synthes hydroxyapatite (HA) coated Schanz Screws can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-Use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though used and contaminated implants may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
Please refer to the table at the end of this IFU.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

The MAXFRAME System hardware is coupled with the MAXFRAME Software for creation of preoperative and treatment planning. MAXFRAME Software can be accessed at MAXFRAME3d.com. Previously, the MAXFRAME3d.com site brought the user directly to the MAXFRAME 3D software application. With the introduction of a newer software version, MAXFRAME 3D II, the website MAXFRAME3d.com becomes a landing page where the user has the ability to select either MAXFRAME 3D or MAXFRAME 3D II, depending on regulatory availability in their country. Refer to the corresponding Software User's Manual (SUM) for a full description of MAXFRAME 3D and/or MAXFRAME 3D II. For the remainder of this document, "MAXFRAME Software" refers to both MAXFRAME 3D and MAXFRAME 3D II.

Magnetic Resonance Environment
Please refer to the table at the end of this IFU.

Treatment before Device is Used
Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Implant Removal

External Distal Radius Fixator
After successful distraction, tighten the screw on the clamp. Remove the distractor by aligning the thumb wheel and loosening the screw on the distractor.

Hybrid Ring Fixator
Implants can be removed by using general surgical instruments.

Pelvic C-Clamp
The Pelvic C-Clamp is removed prior to definitive treatment of the posterior pelvic ring injury. Be sure to remove protective caps from cannulated nails and Kirschner wire from uninjured side.

MAXFRAME –Multi-Axial Correction System
1. Using the Wrench ∅ 8.0/11.0 mm, loosen the nuts on all Clamping Bolts for Schanz screws.
2. Remove all Schanz screws using the Small Universal Chuck with T-Handle.
3. Cut all wires on both sides about 2–3 cm from the skin edge inside the ring. Remove wire remnants attached to the frame, or curl the ends of the wire connected to the frame to prevent inadvertent abrasions to the skin. Prepare the wire on the side of the skin that will be pulled through the soft tissue and bone.
4. Slide the intact frame off the affected limb. If necessary, unlock the struts to facilitate removal of the frame.
5. Remove all wires. Ensure all wires are straight prior to removal.

The Distraction Osteogenesis Ring System
Implants can be removed by using general surgical instruments.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

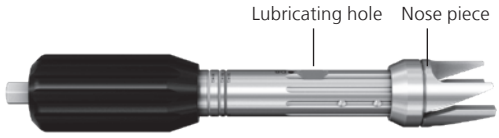
Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

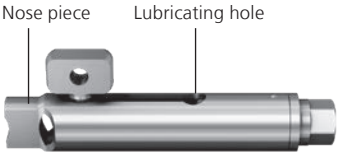
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

Maxframe – Technique
Wire Tensioner (03.312.001)



Back-up Wire Tightener (03.311.008)



Clean and sterilize the Wire Tensioner and Back-up Wire Tightener according to Synthes Important Information. Lubricate the tensioners according to instruction below.

Maintenance Instructions
To lubricate the tensioners prior to sterilization:
1. Apply 4–6 drops of Autoclavable Oil (519.97):
   – Into each lubricating hole;
   – Into the cannulation at the back end of the instrument, with the tensioner in a vertical position; and
   – Into the cannulation of the nosepieces, with the tensioner in a vertical position
2. Spread the oil throughout the mechanism by rotating the knob through several full turns.

Note: Failure to clean and lubricate the tensioner after each use may result in poor performance and reduced operating life of the instrument.

MEFiSTO – Technique
Standard Clamp (392.903), Connecting piece for T-Assembly (392.907), Ring Clamp (392.913) and Tube Clamp (392.911)

Checking function
After cleaning and assembling MEFiSTO, the following must be checked:
– Unhindered sliding of the clamps on the central body.
– Full swivelling range of the saddle joints.
– The screws of the clamps must tighten and loosen easily.
– Smooth turning of the Allen key in the openings of the central body and unimpeded extension to the STOP.
– Correct fit of the Allen key.
– Unhindered turning of the dynamization cap in the sleeve.
– Exact fit of the spanner on the cap.
– Easy assembly of the single pin clamps and the connecting piece for T-assembly.

Checking for wear
Visual inspection for wear of the fixation parts after every use is essential. In particular, the rills in the saddle joint and saddle washer of the standard clamps must be inspected for wear. If there are any visible signs of wear, the component in question should not be used any longer. The decision to reuse it rests with the surgeon. The parts of the standard clamps (excluding the screws), the sleeves and the splined shaft of the central body cannot be ordered as spare parts.

Elbow Hinge Fixator			
Indications	Contraindications	Warnings and Precautions	MR Information
The guided, joint-bridging external fixator assembly is suitable for supplementary treatment of complex, unstable elbow injuries when early functional stress is impossible due to persistent ligamental instability. The most important indications for guided joint bridging with external fixators are: – Delayed treatment of dislocated and rigid elbows – Chronic, persistent joint instability – Acute joint instability after complex ligamentary injuries – Unstable elbow fractures For adults, Elbow Hinge Fixator is preferably configured with the components of the large external fixator (rod diameter: ∅ 11 mm), and with components of the medium-size external fixator (rod diameter: ∅ 8 mm) for children and small adults.	There are no specific contraindications for the Elbow Hinge Fixator.	– Distally, a dorsal approach to the humerus is appropriate. Proximally, it is recommendable to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The SELDRILL Schanz Screw has been developed to minimise heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended. – The tip of the SELDRILL Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Only when bones are osteoporotic, the SELDRILL Schanz Screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – Implant sites should be meticulously cared to avoid pintract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection, the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an External Fixator. – Patients in whom no screws can be inserted due to a bone or soft tissue disease.	MR Conditional Elbow Hinge Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Elbow Hinge Fixator frame may be scanned safely after placement of the frame under the following conditions: – Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned: – 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or – completely outside of the MRI Bore in First Level Control Mode – Highest spatial gradient magnetic field of 900 Gauss/cm or less – Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning – Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed. **Precautions:** Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions the maximum expected temperature rise is less than 6 °C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes. The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes Elbow Hinge Fixator devices may have the potential to cause artifact in the diagnostic imaging. **Warnings:** – Only use frame components stated in the surgical technique of the Elbow Hinge Fixator System – Potential complications of putting a part in the MR field are: – Torsional forces can cause the device to twist in MR field – Displacement forces can pull the device into the MR field – Induced currents can cause peripheral nerve stimulation – Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient – Do not place any radio frequency (RF) transmit coils over the Elbow Hinge Fixator frame. **Note:** In nonclinical testing, the Elbow Hinge Fixator frame was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore. The results showed a maximum observed heating for a frame of 6 °C for 1.5 T and less than 1 °C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg. **Artifact Information** MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Elbow Hinge Fixator frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame. Representative devices used to assemble a typical Elbow Hinge Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Elbow Hinge Fixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located. – For FFE sequence: scan duration 3 minutes, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

External Distal Radius Fixator			
Indications	Contraindications	Warnings and Precautions	MR Information
Unstable distal radius fractures – Intra-articular – Extra-articular – Preliminary fixation before open reduction and internal fixation – Fractures with open and closed soft tissue injury – Multiple trauma (in terms of "damage control surgery" injury-adapted care) Injuries, fractures, dislocations, burns in the area of: – Hand – Wrist – Forearm Fractures in combination with – Extensive soft tissue injuries – Bone loss – Vascular and/or neural involvement Fracture dislocation – Hand Failed closed reduction with casting resulting in secondary dislocation – Radial shortening – Angulation	There are no specific contraindications for the External Distal Radius Fixator.	– Select the appropriate Schanz screw for the patient's bony anatomy. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The SELDRILL Schanz Screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended. – The tip of the Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Only when bones are osteoporotic does the Schanz Screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – Implant sites should be meticulously cared to avoid pin-tract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin-track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an external fixator. – Agitation. – Patients in whom screws cannot be inserted due to a bone or soft tissue disease.	MR Conditional Distal Radius Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Distal Radius Fixator frame may be scanned safely after placement of the frame under the following conditions: – Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned: – 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or – Completely outside of the MRI Bore in First Level Control Mode – Highest spatial gradient magnetic field of 900 Gauss/cm or less – Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning – Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed **Precautions:** Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions, the maximum expected temperature rise is less than 6°C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes. The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes Distal Radius Fixator devices may have the potential to cause artifact in the diagnostic imaging. **Warnings:** – Only use frame components stated in the surgical – technique of the Distal Radius Fixator System – Potential complications of putting a part in the MR field are: – Torsional forces can cause the device to twist in MR field – Displacement forces can pull the device into the MR field – Induced currents can cause peripheral nerve stimulation – Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient – Do not place any radio frequency (RF) transmit coils over the Distal Radius Fixator frame **Note:** In nonclinical testing, the Distal Radius Fixator frame was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore.The results showed a maximum observed heating for a wrist fixator frame of 6 °C for 1.5 T and less than 1 °C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg. **Artifact Information** MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Distal Radius Fixator frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame. Representative devices used to assemble a typical Distal Radius Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Distal Radius Fixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located. – For FFE sequence: scan duration 3 minutes, TR 100 ms,TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

Hybrid Ring Fixator			
Indications	Contraindications	Warnings and Precautions	MR Information
– The hybrid ring fixator is designed for fixation of complex proximal and distal tibial fractures, especially those involving the joint – In soft tissue injuries which make open reduction and internal fixation impossible. – In fracture patterns which do not allow placement of Schanz screws for construction of a standard external fixator frame.	There are no specific contraindications for the Hybrid Ring Fixator.	– Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – Implant sites should be meticulously cared to avoid pintract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant.	The DePuy Synthes "Hybrid Ring Fixator" has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the "Hybrid Ring Fixator" in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Large and Medium-Size External Fixators			
Indications	Contraindications	Warnings and Precautions	MR Information
The Large External Fixator (rod diameter: 11 mm) is particularly suitable for treating the lower extremities. The Medium External Fixator (rod diameter: 8 mm) is particularly appropriate for the extremities of adults, and the upper and lower extremities of children and small adults. The most important indications for Large and Medium External Fixators are: – Second and third-degree open fractures – Infected pseudoarthrosis – Rapid, initial immobilization of soft tissue injuries and fractures in severely injured patients – Immobilization of closed fractures with severe soft tissue trauma (bruising of the soft tissue mantle, burns, skin diseases) – Extensive shaft and periarticular fractures – Transient joint-bridging immobilization in severe soft tissue and ligament injuries – Certain injuries to the pelvic ring, and selected fractures in children – Arthrodeses and osteotomies	There are no specific contraindications for the Large and Medium-Size External Fixators.	– During Iliac crest pin placement: To keep from damaging the femoral cutaneous nerve, avoid insertion up to 15 mm in a dorsal direction from the superior anterior iliac spine. – When dealing with the humerus, primary consideration should be given to the radial and axillary nerves. – Proximally, it is recommendable to introduce the Schanz screws from a ventrolateral direction, caudal to the path of the axillary nerve. – Select the appropriate Schanz screw or Steinmann pin for the patient's bony anatomy. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The SELDRILL Schanz screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended. – Only when bones are osteoporotic does the SELDRILL Schanz screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Implant sites should be meticulously cared to avoid pintract infection. Schanz screws and Steinmann pins may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws and Steinmann pins taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an external fixator. – Patients in whom screws cannot be inserted due to a bone or soft tissue disease.	MR Conditional Large External Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Large External Fixator frame may be scanned safely after placement of the frame under the following conditions: – Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned outside the MRI Bore at Normal Operator or in First Level Control Mode – Highest spatial gradient magnetic field of 720 Gauss/cm or less – Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning – Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed – Specialty coils, such as knee or head coils, should not be used as they have not been evaluated for RF heating and may result in higher localized heating. **Precautions:** Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions, the maximum expected temperature rise is less than 6 °C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes. The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes Large External Fixator devices may have the potential to cause artifact in the diagnostic imaging. **Warnings:** – Only use frame components stated in the surgical technique of the Large External Fixator System – Potential complications of putting a part in the MR field are: – Torsional forces can cause the device to twist in MR field – Displacement forces can pull the device into the MR field – Induced currents can cause peripheral nerve stimulation – Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient – Do not place any radio frequency (RF) transmit coils over the Large External Fixator frame. **Note:** In nonclinical testing, the Large External Fixator devices were tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore. The results showed a maximum observed heating of less than 6 °C for 1.5 T and 3.0 T with a machine reported whole body averaged SAR of 2 W/kg. **Artifact Information** MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Large External Fixator frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame. Representative devices used to assemble a typical Large External Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Large External ixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located. – For FFE sequence: scan duration 3 minutes, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

Medium External Fixators			
			MR Information

			MR Conditional
			
			Medium External Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Medium External Fixator frame may be scanned safely after placement of the frame under the following conditions:
			– Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned:
			  – 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or
			  – Completely outside of the MRI Bore in First Level Control Mode
			– Highest spatial gradient magnetic field of 900 Gauss/cm or less
			– Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning
			– Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed.
			
			Precautions: Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions, the maximum expected temperature rise is less than 6 °C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes.
			The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes Medium External Fixator devices may have the potential to cause artifact in the diagnostic imaging.
			
			Warnings:
			– Only use frame components stated in the surgical technique of the Medium External Fixator System
			– Potential complications of putting a part in the MR field are
			  – Torsional forces can cause the device to twist in MR field
			  – Displacement forces can pull the device into the MR field
			  – Induced currents can cause peripheral nerve stimulation
			  – Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient
			– Do not place any radio frequency (RF) transmit coils over the Medium External Fixator frame
			
			Note: In nonclinical testing, the Medium External Fixator frame was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore.
			The results showed a maximum observed heating for a wrist fixator frame of 6 °C for 1.5 T and less than 1 °C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg.
			
			Artifact Information
			MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Medium External Fixator frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame.
			Representative devices used to assemble a typical Medium External Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Medium External Fixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located.
			– For FFE sequence: scan duration 3 minutes, TR 100 ms,TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

MEFiSTO			
Indications	Contraindications	Warnings and Precautions	MR Information
For all indications where external fixation is the suitable form of treatment: – Fractures of the tibia and femur with severe soft tissue injury – Immediate immobilization of fractures with or without soft tissue injury in severely injured, multiply injured or polytrauma patients – Immobilization of closed fractures with severe soft tissue trauma (crushing of soft tissue, burns, dermatological affections) – Extensive diaphyseal and periarticular fractures – Temporary transarticular stabilization of severe soft tissue injuries and damaged ligaments – Infected pseudarthroses – Corrective osteotomies or corticotomies in the treatment of axial deviation and length difference (correction of axis, bone lengthening) – Complex proximal and distal tibial fractures – Certain pelvic ring disruptions – Treatment of tibial and femoral shaft fractures in children	There are no specific contraindications for the MEFiSTO.	– Select the appropriate Schanz screw for the patient's bony anatomy. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The SELDRILL Schanz screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended. – The tip of the SELDRILL Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Implant sites should be meticulously cared to avoid pintract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an external fixator. – Agitation. – Patients in whom screws cannot be inserted due to a bone or soft tissue disease.	The DePuy Synthes "MEFiSTO" has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the "MEFiSTO" in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Pelvic C-Clamp			
Indications	Contraindications	Warnings and Precautions	MR Information
The Pelvic C-Clamp is indicated for emergency stabilization of sacrum fractures or disruptions of the sacroiliac joint with associated circulatory instability.	There are no specific contraindications for the Pelvic C-Clamp.	– Avoid use where: a. Fractures of the ilium are present as there is risk of pin perforation through the fracture line. b. There are comminuted sacral fractures with the risk of compression of the sacral nerve plexus. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – Select the appropriate Schanz screw for the patient's bony anatomy. – If the nails are placed too ventrally to the correct insertion point, there is a risk of perforation of the ilium, which can result in organ injury. – Placement of the pins in an excessively dorsal position may result in injury to gluteal nerves and vessels. – Inserting the nail too distally endangers the sciatic nerve and the gluteal vessels in the sciatic notch. Malpositioning of the nail in osteoporotic bone, combined with excessive compression, can result in unwanted nail penetration. – Do not use the Pelvic C-Clamp to lift the patient.	The DePuy Synthes "Pelvic C-Clamp" has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the "Pelvic C-Clamp" in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Schanz Screws and Steinmann Pins			
Indications	Contraindications	Warnings and Precautions	MR Information
Synthes SELDRILL, Self-tapping, Hydroxyapatite-coated Schanz Screws and Steinmann Pins are indicated for use with an external fixation system.	There are no specific contraindications for the Schanz Screws and Steinmann Pins.	– Select the appropriate Schanz Screw (self-tapping, SELDRILL, Hydroxyapatite) or Steinmann pin for the patient's bony anatomy. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The SELDRILL Schanz Screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended. – The tip of the SELDRILL Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Only when bones are osteoporotic does the SELDRILL Schanz Screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – The tip of the Self-tapping Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Implant sites should be meticulously cared to avoid pintract infection. Schanz Screws and Steinmann pins may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin tract infection the following points should be observed: a. Placement of Schanz Screws and Steinmann pinstaking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant – During Iliac crest pin placement: To keep from damaging the femoral cutaneous nerve, avoid insertion up to 15 mm in a dorsal direction from the superior anterior iliac spine. – When dealing with the humerus, primary consideration should be given to the radial and axillary nerves. Distally, a dorsal approach to the humerus is appropriate. Proximally, it is recommendable to introduce the Schanz Screws from a ventrolateral direction, caudal to the path of the axillary nerve. – Synthes Hydroxyapatite (HA) coated Schanz Screws are only available sterile packed. Do not attempt to re-sterilize. – Synthes SELDRILL, Self-tapping, Hydroxyapatite-coated Schanz Screws and Steinmann Pins are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.	MR Conditional Non-clinical testing has been performed to assess Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F 2119-07 and Radio-Frequency (RF) induced heating according to ASTM F 2182-11a. These tests have not been done on the individual implants but on the entire external fixator construct.

Segment Transport MEFiSTO			
Indications	Contraindications	Warnings and Precautions	MR Information
Tibial and femoral segment transport in: – post-traumatic defects with or without deformity – necrosis – infections – pseudarthroses – tumours	There are no pecific contraindications for the Segment Transport MEFiSTO.	– Select the appropriate Schanz screw for the patient's bony anatomy. – The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Only when bones are osteoporotic, the SELDRILL™ Schanz screw has to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – Implant sites should be meticulously cared to avoid pin tract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an external fixator. – Agitation. – Patients in whom screws cannot be inserted due to a bone or soft tissue disease.	The DePuy Synthes "MEFiSTO" has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the "MEFiSTO" in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Small External Fixator			
Indications	Contraindications	Warnings and Precautions	MR Information
Unstable distal radius fractures – Intra-articular – Extra-articular – Preliminary fixation before open reduction and internal fixation – Fracture with open and closed soft tissue injury – Multiple trauma (in terms of "damage controlled surgery" – injury-adapted care) Other indications Injuries, fractures, dislocations, burns – Carpal region – Wrist – Forearm – Ankle (possibly in combination with a medium or large fixator) Fractures in combination with – Extensive soft tissue injuries – Bone loss – Vascular and/or neural involvement Fracture dislocation – Carpal bones Failed closed reduction with casting resulting in secondary dislocation – Radial shortening – Angulation	There are no specific contraindications for the Small External Fixator.	– Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The SELDRILL Schanz screw has been developed to minimise heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended. – The tip of the SELDRILL Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Select the appropriate Schanz screw for the patient's bony anatomy. – Only when bones are osteoporotic does the SELDRILL Schanz screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – The tip of the Self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Implant sites should be meticulously cared to avoid pintract infection. Schanz Screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an external fixator. – Agitation. – Patients in whom screws cannot be inserted due to a bone or soft tissue disease.	MR Conditional Small External Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Small External Fixator frame may be scanned safely after placement of the frame under the following conditions: – Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned outside the MRI Bore at Normal Operator or in First Level Control Mode – Highest spatial gradient magnetic field of 720 Gauss/cm or less – Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning – Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed – Specialty coils, such as knee or head coils, should not be used as they have not been evaluated for RF heating and may result in higher localized heating. **Precautions:** Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions, the maximum expected temperature rise is less than 6 °C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes. The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes Small External Fixator devices may have the potential to cause artifact in the diagnostic imaging. **Warnings:** – Only use frame components stated in the surgical technique of the Small External Fixator System. – Potential complications of putting a part in the MR field are: – Torsional forces can cause the device to twist in MR field – Displacement forces can pull the device into the MR field – Induced currents can cause peripheral nerve stimulation – Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient. – Do not place any radio frequency (RF) transmit coils over the Small External Fixator frame. **Note:** In nonclinical testing, the Small External Fixator frame was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore. The results showed a maximum observed heating for the wrist fixator frame of less than 4 °C for 1.5 T and less than 2 °C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg. **Artifact Information** MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Small External Fixator frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame. Representative devices used to assemble a typical Small External Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Small External Fixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located. – For FFE sequence: scan duration 3 minutes, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

MAXFRAME –Multi-Axial Correction System			
Indications	Contraindications	Warnings and Precautions	MR Information
The DePuy Synthes MAX-FRAME System is indicated for the following treatments in adults and in both children (3–12) and adolescents (12–21) in which the 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 non-unions – correction of bony or soft tissue deformities – correction of segmental defects	MAXFRAME is not intended for use in the spine.	– Do not combine MAXFRAME Rings with Distraction Osteogenesis rings for construction of the frame with one exception: Distraction Osteogenesis half rings (03.311.312, 315, 318, 320) can be used to close off the MAXFRAME Foot Plates. The MAXFRAME Software cannot create a treatment plan using Distraction Osteogenesis rings. – If counter-torque is not provided, the torque could damage the strut. – Do not use the Torque Wrench, 10 Nm for loosening as it may damage the torque wrench. The Torque Wrench, 10 Nm is calibrated for one direction only. – Linear and polyaxial struts are not intended for use with the MAXFRAME Software. – MAXFRAME Half and Third Rings are not intended for use with the MAXFRAME Software. – Do not bend wires to attach them to the ring as this could increase the risk of wire breakage. See the next page for offset fixation options. – To maintain proper alignment of the Schanz screw, you must use the Clamping Bolt, cannulated, for Schanz Screws, for Post (03.311.059) to connect the wire post to the Schanz screw. Do not use the Clamping Bolt, cannulated, for Schanz Screws, for Rings (03.311.058). – Take care to keep the wire bolt head aligned, to prevent bending the wire. – If it is determined that a wire must be removed because of sub-optimal placement, the recommended technique is to cut wire inside of ring and remove by pulling away from bone to reduce the chance of introducing debris into soft tissue. – Pre-drilling for self-drilling screws is recommended for dense or thick cortical bone to avoid bone necrosis. Consider cooling the drill with saline. – If counter-torque is not provided the force of the Torque Wrench, 10 Nm could damage the strut. – If using a bridging plate to close a 5/8 rings, do not tension any wires until after the 5/8 ring and bridging plate have been connected, otherwise the tension can deform the ring such that the bridging plate will no longer fit. – It is important to cut the wires inside of ring, close to the skin before pulling through bone to reduce the chance of debris being introduced to the patient. – Do not pull the stopper on the reduction wire through bone. Pull on the side with the spiral markings. – If using the Quick Adjust struts, you must use the ID Bands to prevent inadvertent unlocking of the Quick Adjust locking collar. – Do not use the MAXFRAME hardware with any software program other than MAXFRAME Software as it could result in an incomplete or incorrect treatment plan.	 MR Conditional Non-clinical testing has demonstrated that the DePuy Synthes MAXFRAME is MR Conditional according to the terminology specified in ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. A patient with this device can be safely scanned in an MR system meeting the following conditionss: – Static magnetic field of 1.5 T or 3.0 T – Maximum spatial field gradient of 2000 gauss/cm (20 T/m) – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode). **Precautions:** – The entire MAXFRAME construct must remain outside of the bore of the MR system. – All components of the MAXFRAME construct must be identified as MR Conditional prior to entering the MR environment. **Warning:** – Do not place any radio frequency (RF) transmit coils over the external fixation frame. Under the scan conditions defined above, the DePuy Synthes MAXFRAME is expected to produce a maximum temperature rise of less than 6 °C after 15 minutes of continuous scanning.

The Distraction Osteogenesis Ring System			
Indications	Contraindications	Warnings and Precautions	MR Information
The Distraction Osteogenesis Ring System is indicated for fracture fixation (open and closed); pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental bony or soft tissue defects.	There are no specific contraindications for the Distraction Osteogenesis Ring System.	– Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – Wire sites and pin sites should be cared for meticulously to avoid wire-tract and pin-tract infection. Wires and Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. – A wire and pin-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant.	MR Conditional Distraction Osteogenesis Ring devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Distraction Osteogenesis Ring frame may be scanned after placement of the frame under the following conditions: – Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned: – 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or – Completely outside of the MRI Bore in First Level Control Mode – Highest spatial gradient magnetic field of 900 Gauss/cm or less – Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning – Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed. **Precautions:** Patients may be scanned in the MRI chamber under the above conditions. Under such conditions, the maximum expected temperature rise is less than 6 °C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes. The above field conditions should be compared with those of the user's MR system in order to determine if the item can be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes Distraction Osteogenesis Ring devices may have the potential to cause artifact in the diagnostic imaging. **Warnings:** – Only use frame components stated in the surgical technique of the Distraction Osteogenesis Ring System – Potential complications of putting a part in the MR field are – Torsional forces can cause the device to twist in MR field – Displacement forces can pull the device into the MR field – Induced currents can cause peripheral nerve stimulation – Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient – Do not place any radio frequency (RF) transmit coils over the Distraction Osteogenesis Ring frame. **Note:** In nonclinical testing, the Distraction Osteogenesis Ring System was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore. The results showed a maximum observed heating for a frame of 6 °C for 1.5 T and less than 1 °C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg. **Artifact Information** MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Distraction Osteogenesis Ring frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the frame. Representative devices used to assemble a typical Distraction Osteogenesis Ring frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by Synthes Distraction Osteogenesis Ring System devices may present issues if the MR imaging area of interest is in or near the area where the frame is located. – For FFE sequence: scan duration 3 minutes, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

Large Distractor – Tibia			
Indications	Contraindications	Warnings and Precautions	MR Information
There are no specific indications for the Large Distractor – Tibia. Refer to the intended use section of this IFU for the device intended use.	There are no specific Contraindications for the Large Distractor – Tibia.	– Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin. – Handle devices with care and dispose worn bone cutting instruments in an approved sharps container. – The tip of the Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability. – Only when bones are osteoporotic, the Schanz screw has to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability. – Implant sites should be meticulously cared to avoid pin-tract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient. – To minimize the risk of pin track infection the following points should be observed: a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries). b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis. c. Release of skin tension at soft tissue entry point of implant. – The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions: – Patients who for social and physical reasons are not suitable for an external fixator. – Agitation. – Patients in whom screws cannot be inserted due to a bone or soft tissue disease.	The DePuy Synthes "Large Distractor – Tibia" has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the "Large Distractor – Tibia" in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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