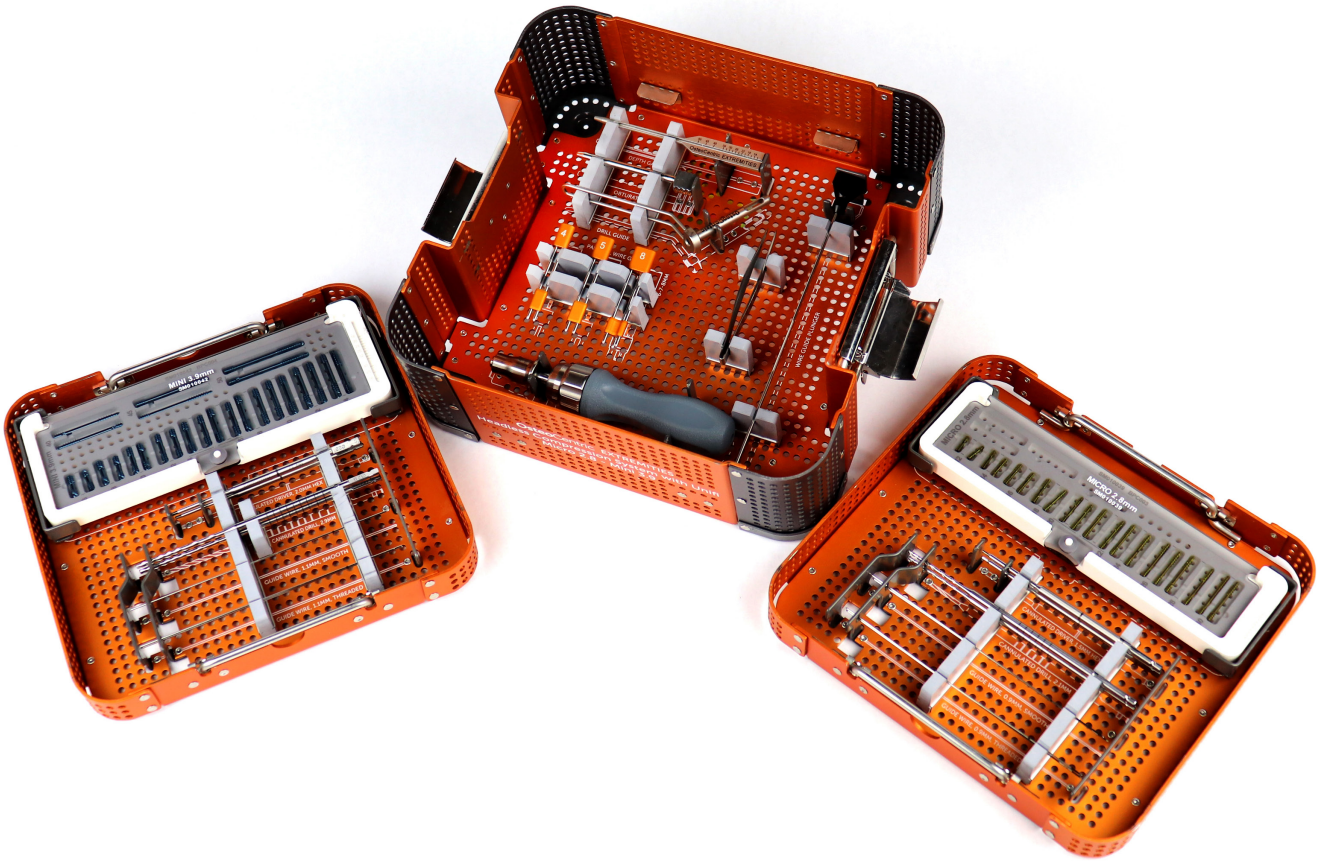
OsteoCentric Extremities

Headless Compression System

Surgical Technique



OsteoCentric TECHNOLOGIES

OsteoCentric Extremities Headless Compression System

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Description

The OsteoCentric Extremities Headless Compression System Micro-2.8 Mini-3.9, consists of headless compression screw fasteners and select instrumentation to facilitate implantation. The Headless Compression Screw Fasteners are threaded, cannulated implants designed to provide fixation of various fractures and osteotomies while they heal. The implants and instruments are provided non-sterile. Implants are manufactured from Titanium per ASTM F136.

General System Information

The surgeon must select the type and size of the implant that best meets the patient's surgical needs. Refer to the Instructions for Use (package insert) for indications, contraindications, precautions, warnings and cleaning instructions. To obtain these materials or to obtain more information about products, please contact Customer Service at (800) 969-0639, or go to the OsteoCentric website www.osteocentric.com.

Indications for Use

The Headless Compression Screw System Micro-2.8 screw fasteners are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The Headless Compression Screw System Mini-3.9 screw fasteners are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodeses of the carpals and phalanges, steochondritis dissecans, and ligament fixation.

The screw fasteners are intended for single use only and may not be reused under any circumstances.

The system drills and guide wires are single use instruments.

Implant Overview

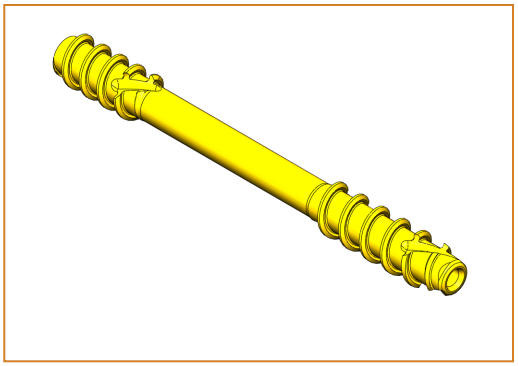
The OsteoCentric Headless Compression Screw Fasteners consist of dual-threaded, cannulated screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The screws are provided non-sterile in a steam sterilization tray. Screws are manufactured from ASTM F136 Titanium.

Different thread pitches on the implant tip and head enables compression as the screw fastener is advanced. The screw fastener is inserted below the bone surface reducing the probability of soft tissue irritation.

The OsteoCentric Extremities Headless Compression Screw Fasteners includes:

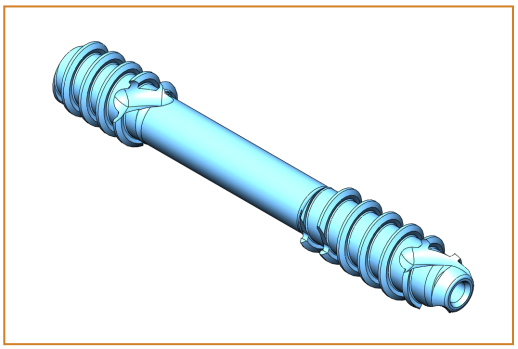
Ø2.8mm Headless Compression Screw Fasteners

- Cannulated
- Self-Tapping
- 12 – 30mm lengths in 2mm increments
- ASTM F136 Titanium



Ø3.9mm Headless Compression Screw Fasteners

- Cannulated
- Self-Tapping
- 16 – 34mm lengths in 2mm increments
- 40 – 50mm lengths in 5mm increments
- ASTM F136 Titanium



Insertion of an OsteoCentric Extremities Headless Compression Screw Fastener

1. Identify the area of operation and appropriately sized screw fastener for the operative area and indications of the surgery.

Identify the appropriately sized screw fastener to be used on the anatomic area of operation. Prior to surgery, ensure that the instrument set is complete with screw fasteners and instrumentation (i.e. drill bits and screw drivers).

2. Dissect down to the bone and reduce the fracture.

Standard orthopedic instruments and techniques should be used for reduction and to position the bone for fixation.

3. Place the Guide Wire in desired orientation.

Insert the appropriately sized guide wire into the bone across the fracture to the desired depth (Figure 1). The fracture reduction, guide wire depth and orientation can be confirmed under fluoroscopy.

Note: A parallel wire guide is available to aid with guidewire placement and to protect soft tissues during guide wire placement. If the fragment is unstable, it may be helpful to use the Parallel Wire Guide to place an additional guide wire parallel to the first one to stabilize and minimize rotation of the fragment (Figure 2).

Precaution: Do not forcefully insert guide wire especially when using guide wires in bones of different densities as the guide wire can become deformed. The guide wire can also be deformed during a transition through a joint in which movement of the joint during fixation, or pin deflection crossing the joint space, creates a slight change in direction.

This change of direction can hamper smooth passage of the drill bit over the guide pin and can erode the pin, creating a stress riser in the pin that may result in breakage.

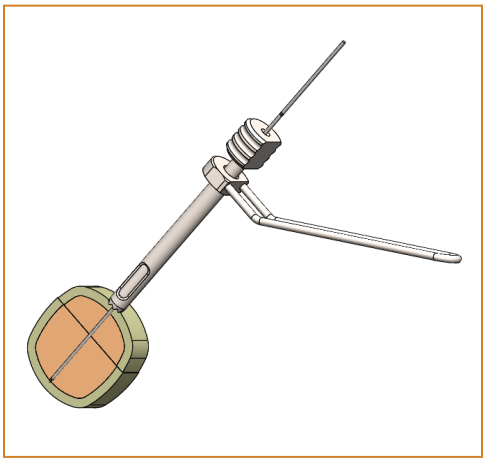


Figure 1

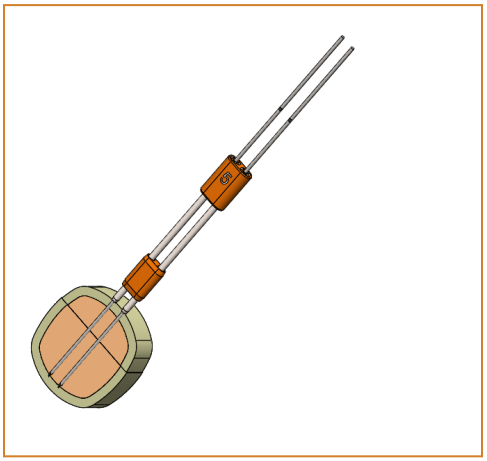


Figure 2

4. Measure the screw fastener length.

The length of the screw fastener is measured using the Depth Gage. Slide the tapered end of the Depth Gage over the Guide Wire until the tip contacts the bone surface. The alignment of the guide wire laser mark on the depth gage indicates the screw fastener length (Figure 3). After measuring the length of the screw fastener, the guide wire may be advanced further to minimize inadvertent withdrawal of the Guide Wire while drilling.

Note: When selecting the screw fastener length, it is mandatory that the distal thread is not positioned across the fracture gap, otherwise no compression will be achieved.

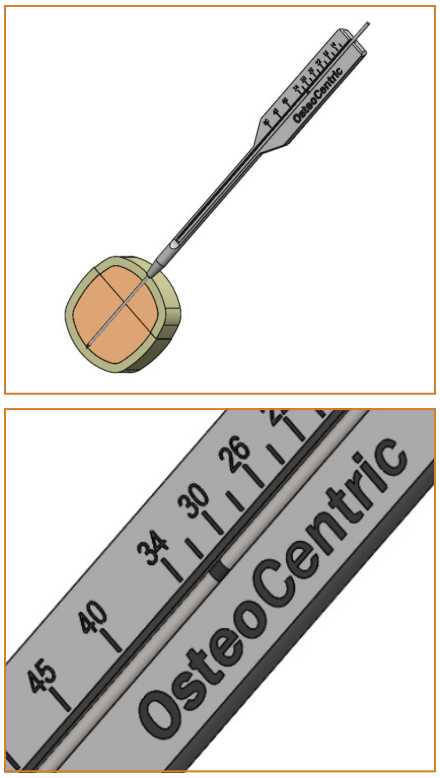


Figure 3

5. Drill the bone using the appropriate cannulated drill bit.

Use the appropriately sized cannulated drill bit and place over the guide wire. The 2.1mm drill should be used for all Micro screw fasteners and the 2.9mm drill should be used for all Mini screw fasteners. Use drill depth markings to ensure appropriate depth based on implant length (Figure 4). The Guidewire Plunger may be used to maintain guide wire placement while removing drill bit.

Note: It is recommended to drill entire length of fastener to ensure smooth implantation and to prevent distraction of the distal fragment during implant insertion.

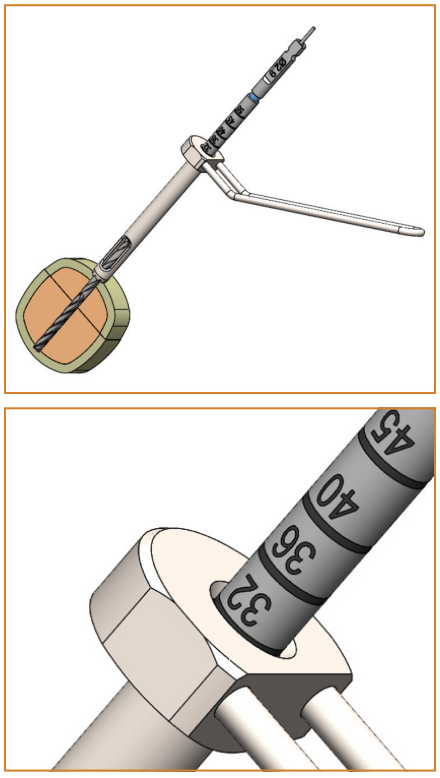


Figure 4

6. Insert the screw fastener.

Place the appropriately sized screw fastener (identified in step one and step four) over the guide wire down to the bone surface. Using the appropriately sized cannulated screw driver advance the screw fastener by turning the screw driver clockwise until the screw fastener is firmly seated in the bone and the head of the screw fastener is at or just below the surface of the bone (Figure 5).

If resistance occurs during implant placement, or if distraction occurs, it is strongly recommended to remove implant and re-drill the entire length of the implant. Do not use excessive force as the screw threads may strip eliminating fixation in the bone.

Once the proximal threads contact the near bone surface every full revolution of the screw driver compresses the fracture by 0.25mm. Due to the different thread pitches on the tip and the head the screw fastener will create approximately 1.5mm of compression between the bone fragments.

Note: Laser marking on distal end of the screw driver indicates the proximal end of the fastener is 2mm sub-cortical (Figure 6).

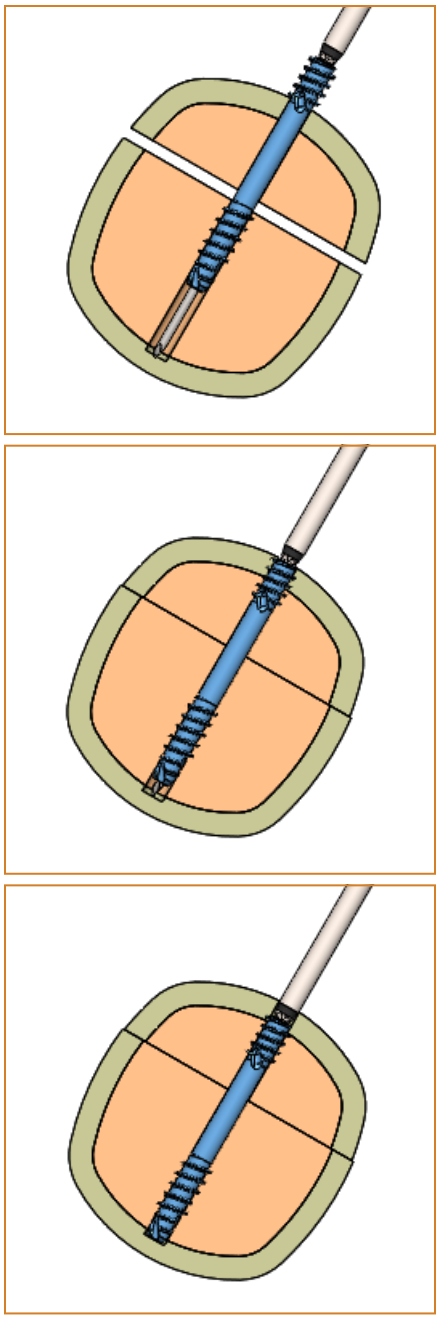
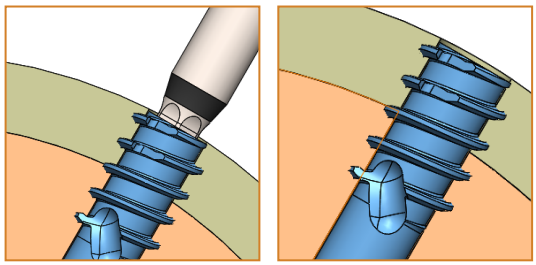
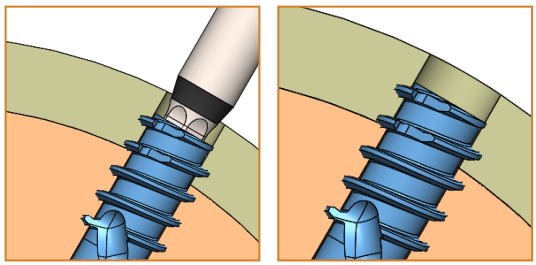


Figure 5

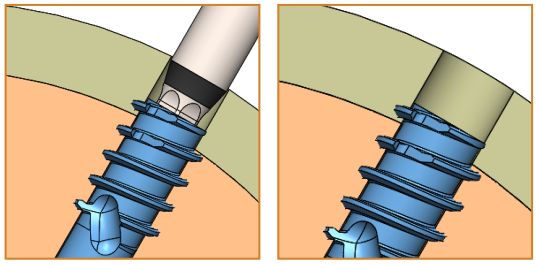
Figure 6



a. Flush with bone



b. 1mm subcortical



c. 2mm subcortical

If the Drill Guide is used while inserting the screw fastener laser marking on the driver shaft will indicate when the proximal end of the screw fastener is 2mm sub-cortical (Figure 7).

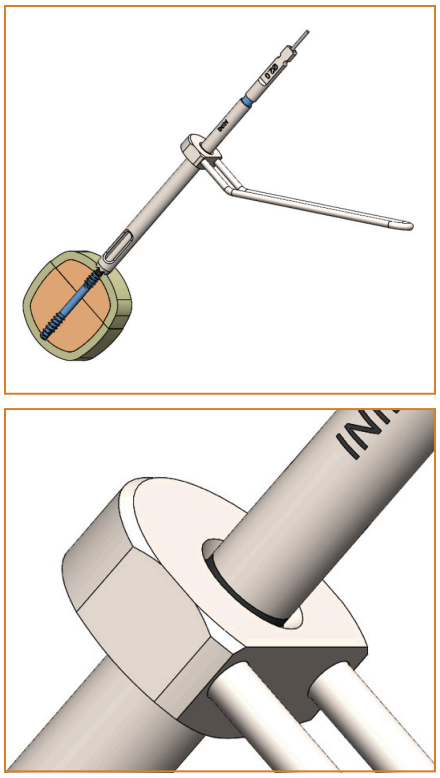


Figure 7

7. Confirm placement and remove the guide wire.

Confirm correct placement and length of the screw fastener under fluoroscopy. Remove and discard the guide wire.

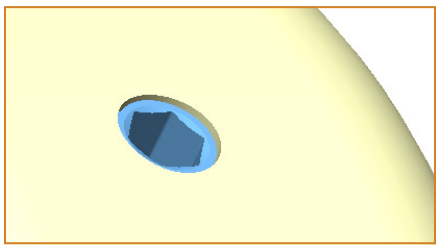


Figure 8

Contraindications:

The physician's education, training, and professional judgment are necessary to determine the appropriate treatment protocol and patient selection. Contraindications may be relative to each patient, and clinicians should always consider all risks and possible reactions when considering the proper treatment protocol. Specific contraindications include:

- Allergies and sensitivities to materials in the device
- Active or latent infection
- Obesity
- Pathologic fractures
- Skeletal immaturity
- Osteoporosis or other disease resulting in osteopathology
- Previous implantation
- Tissue viability at or near the operative site
- Compromised blood flow at or near the operative site
- Mental or neuromuscular disorders
- Patient compliance
- Spinal fixation – this device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Implants

All implant components are manufactured from Titanium per ASTM F136.

Part Number	Part Description	Length (mm)	Material
EX01-5028-12	2.8mm x 12mm Headless Compression Screw	12	Ti
EX01-5028-14	2.8mm x 14mm Headless Compression Screw	14	Ti
EX01-5028-16	2.8mm x 16mm Headless Compression Screw	16	Ti
EX01-5028-18	2.8mm x 18mm Headless Compression Screw	18	Ti
EX01-5028-20	2.8mm x 20mm Headless Compression Screw	20	Ti
EX01-5028-22	2.8mm x 22mm Headless Compression Screw	22	Ti
EX01-5028-24	2.8mm x 24mm Headless Compression Screw	14	Ti
EX01-5028-26	2.8mm x 26mm Headless Compression Screw	26	Ti
EX01-5028-28	2.8mm x 28mm Headless Compression Screw	28	Ti
EX01-5028-30	2.8mm x 30mm Headless Compression Screw	30	Ti
EX01-5039-16	3.9mm x 16mm Headless Compression Screw	16	Ti
EX01-5039-18	3.9mm x 18mm Headless Compression Screw	18	Ti
EX01-5039-20	3.9mm x 20mm Headless Compression Screw	20	Ti
EX01-5039-22	3.9mm x 22mm Headless Compression Screw	22	Ti
EX01-5039-24	3.9mm x 24mm Headless Compression Screw	24	Ti
EX01-5039-26	3.9mm x 26mm Headless Compression Screw	26	Ti
EX01-5039-28	3.9mm x 28mm Headless Compression Screw	28	Ti
EX01-5039-30	3.9mm x 30mm Headless Compression Screw	30	Ti
EX01-5039-32	3.9mm x 32mm Headless Compression Screw	32	Ti
EX01-5039-34	3.9mm x 34mm Headless Compression Screw	34	Ti
EX01-5039-40	3.9mm x 40mm Headless Compression Screw	40	Ti
EX01-5039-45	3.9mm x 45mm Headless Compression Screw	45	Ti
EX01-5039-50	3.9mm x 50mm Headless Compression Screw	50	Ti

Instruments

Part #	Part Description	Material	Class
EX01-0004	Screw Depth Gage	Stainless Steel (ASTM F899)	1
EX01-0005	Obturator, Assy	Stainless Steel (ASTM F899)	1
EX01-0008	Drill Guide, Percutaneous, Assy	Stainless Steel (ASTM F899) Stainless Steel (ASTM A269)	1
EX01-0012	Guidewire Plunger, Assy	Stainless Steel (ASTM F899) RADEL R5500 (ASTM D6394) LOCTITE M-31CL Medical Grade Adhesive	1
EX01-0015	Parallel Wire Guide, 4mm, Assy	Stainless Steel (ASTM A511/A511M) Anodized 6061-T6 Aluminum (ASTM B209) LOCTITE M-31CL Medical Grade Adhesive	1
EX01-0016	Parallel Wire Guide, 5mm, Assy	Stainless Steel (ASTM A511/A511M) Anodized 6061-T6 Aluminum (ASTM B209) LOCTITE M-31CL Medical Grade Adhesive	1
EX01-0021	Parallel Wire Guide, 6-7-8mm, Assy	Stainless Steel (ASTM A511/A511M) Anodized 6061-T6 Aluminum (ASTM B209) LOCTITE M-31CL Medical Grade Adhesive	1
EX01-0025	Ratcheting Handle, AO Quick Connect	Stainless Steel (ASTM F899) Silicone (USP Class VI)	1
EX01-0026	K-wire, .9mm, single trocar, smooth	Stainless Steel (ASTM F138)	1
EX01-0028	K-wire, 1.1mm, single trocar, smooth	Stainless Steel (ASTM F138)	1
EX01-0029	K-wire, 1.1mm, single trocar threaded	Stainless Steel (ASTM F138)	1
EX01-0030	Drill Bit, Cannulated, 2.1mm	Stainless Steel (ASTM F899)	1
EX01-0031	Drill Bit, Cannulated, 2.9mm	Stainless Steel (ASTM F899)	1
EX01-0032	Driver Shaft, Cannulated, 1.5mm Hex	Stainless Steel (ASTM F899)	1
EX01-0033	Driver Shaft, Cannulated, 2.0mm Hex	Stainless Steel (ASTM F899)	1
EX01-0050	Feilchenfeld Forceps, 3-1/2 Inches	Stainless Steel (ASTM F899)	1

Note:

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice.

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