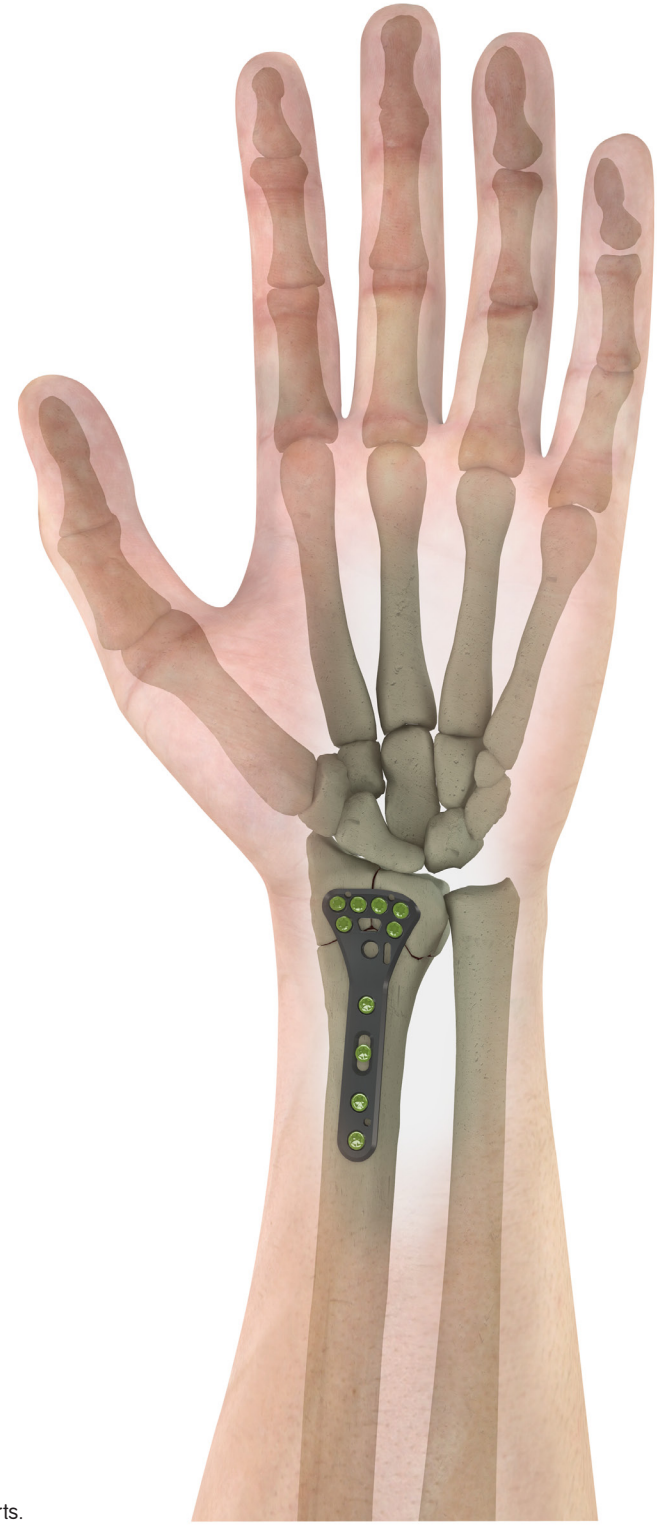
smith&nephew

D-RAD SMART PACK◇

Single-Use Volar Distal Radius Plating System



Hospital overview and technical assessment

This brochure is intended to be informational only and should not be used for promotional efforts.

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Single-Use Volar Distal Radius Plating System

510K clearance: January 7, 2014 (K132296)

Background

Distal radius fractures are among the most common orthopaedic injuries and are usually the result of high-energy impacts and falls. Generally, goals of treatment include the following:

- Complete restoration of the normal anatomic configuration
- Stable fracture reduction allowing early motion and rehabilitation
- Full recovery with painless motion of the wrist

Treatment options include but are not limited to the following:

Closed reduction

- Casting
- Percutaneous pinning
- Pins and plaster
- External fixation
- External fixation and pinning

Open reduction

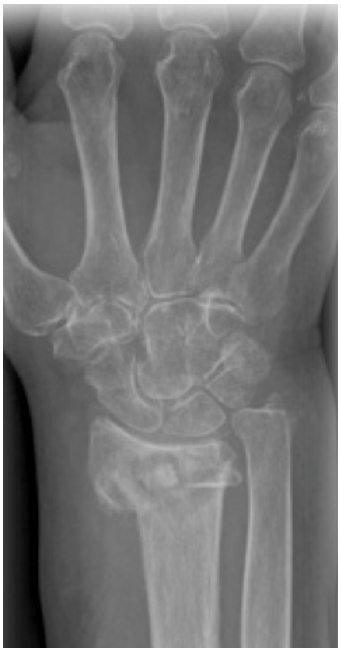
- Pinning
- Plate and screw fixation (volar, dorsal, and/or fragment specific)

Adjuvant treatment

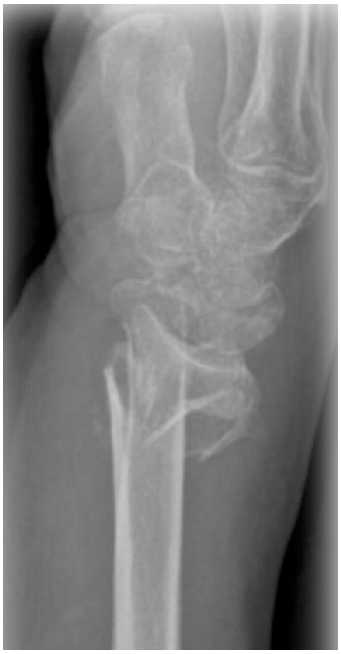
- Bone cement
- Plate and screw fixation (volar, dorsal, and/or fragment specific)

Basic concepts of locked volar distal radius plating:

- Less disrupted anatomy
- Precise fracture reduction
- Articular surface support with subchondral bone
- Minimized soft-tissue complications with volar implant placement



Anterior/posterior view



Lateral view

Technology overview

The D-RAD SMART PACK® Single-Use Volar Distal Radius Plating System was designed to treat the most commonly plated extra-articular and intra-articular distal radius fractures. The system includes four anatomically contoured titanium volar locking plates. Plates are left/right specific and are available in two widths: standard and wide. Each individual plate is packaged within a sterile single-use instrument kit. D-RAD single-use instrument kits are accompanied by a tray containing sterile fasteners used to affix the plate to the radius, maintain fracture reduction and provide articular support. Additionally, the tray contains single-use plate templates to assist with plate/kit selection. The sterile single-use nature of the system is intended to eliminate the labor, material costs and time required to reprocess implants and implant-specific instrumentation related to the procedure.

Summary of indications, contraindications, warnings and other important information

Indications

The D-RAD SMART PACK System is intended for the fixation of fractures involving the distal radius.

Contraindications

- The D-RAD SMART PACK System is not intended for use in bones other than the radius.
- Physical conditions that would preclude adequate implant support or retard healing, such as, blood supply impairment, insufficient bone quality or quantity, previous infection, obesity, severe bow or gross distortion of the radius.
- Mental conditions that preclude cooperation with the rehabilitation program.

Warnings

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

- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read instructions completely prior to use.
- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
- Use only Ti-6Al-4V screws with Ti-6Al-4V devices.
- D-RAD SMART PACK System's devices and accessory components should not be placed across growth plates in pediatric patients.

Precautions

US federal law restricts this device to sale by or on the order of a physician.

- Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Use extreme care handling and storing implant components. Cutting, bending or scratching the surface of metal components may cause internal stresses which may significantly reduce the strength and fatigue resistance.
- Intraoperative fracture or breaking of instruments can occur.
- Postoperative instructions to patients and appropriate nursing care are critical. Early load bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early load bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the patient, fixation devices should be removed once their service as an aid to healing is complete.
- A single-use device which comes in direct contact with human blood or tissue should not be reused and should be disposed of properly.
- After use, these components may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
- Surgical technique information is available on request.

Adverse reactions

- Loosening, bending, cracking or fracture of implant components.
- Loss of anatomic position with malunion may occur.
- Infections, both deep and superficial, have been reported with internal fixation devices.
- Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis may result from the surgery and concomitant use of internal fixation devices.
- Metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- Penetration of a K-wire, screw, or peg into a joint can occur.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.

Packaging and labeling

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

Sterilization

For components provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{6}. Sterile packaged components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery. In instances of breached sterility, the system's contents may be resterilized up to one additional cycle. Refer to the recommendations below for resterilization of the system's contents. A single-use device which comes in direct contact with human blood or tissue should not be reused and should be disposed of properly.

Recommended steam sterilization cycle parameters

Containment devices should be wrapped with a central supply wrap or placed in a reusable rigid container for sterilization.

Note to US customers

Sterilizers and wraps used in the sterilization process must be FDA cleared. Dynamic Air Removal (Prevacuum) Steam Cycle: 132° C (270° F) for 4 minutes or 135° C (275° F) for 3 minutes and a minimum vacuum drying time of 30 minutes.

Note to non-US customers

United Kingdom Steam Cycle: 134° C (273° F) for 3 minutes and a minimum vacuum drying time of 30 minutes. (Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.)

Product ordering info

Set number 7115-8000

	Catalog #	Description	Qty
Single-use kits 	7115-8019	D-RAD SMART PACK 4H Left Standard Plate	2
	7115-8020	D-RAD SMART PACK 4H Left Wide Plate	1
	7115-8021	D-RAD SMART PACK 4H Right Standard Plate	2
	7115-8022	D-RAD SMART PACK 4H Right Wide Plate	1
Plate templates 	7115-8017	D-RAD Plate Templates Left	3
	7115-8018	D-RAD Plate Templates Right	3
Fasteners 	7467-1812	D-RAD Ti 1.8mm x 12mm LCK PEG T7	3
	7467-1814	D-RAD Ti 1.8mm x 14mm LCK PEG T7	8
	7467-1816	D-RAD Ti 1.8mm x 16mm LCK PEG T7	7
	7467-1818	D-RAD Ti 1.8mm x 18mm LCK PEG T7	7
	7467-1820	D-RAD Ti 1.8mm x 20mm LCK PEG T7	7
	7467-1822	D-RAD Ti 1.8mm x 22mm LCK PEG T7	4
	7467-1824	D-RAD Ti 1.8mm x 24mm LCK PEG T7	3
	7468-2410	D-RAD Ti 2.4mm x 10mm CTX SCR T7 S-T	7
	7468-2412	D-RAD Ti 2.4mm x 12mm CTX SCR T7 S-T	8
	7468-2414	D-RAD Ti 2.4mm x 14mm CTX SCR T7 S-T	7
	7468-2416	D-RAD Ti 2.4mm x 16mm CTX SCR T7 S-T	7
	7468-2418	D-RAD Ti 2.4mm x 18mm CTX SCR T7 S-T	7
	7468-2420	D-RAD Ti 2.4mm x 20mm CTX SCR T7 S-T	7
	7468-2422	D-RAD Ti 2.4mm x 22mm CTX SCR T7 S-T	4
	7468-2424	D-RAD Ti 2.4mm x 24mm CTX SCR T7 S-T	3
	7469-2410	D-RAD Ti 2.4mm x 10mm LCK SCR T7 S-T	7
	7469-2412	D-RAD Ti 2.4mm x 12mm LCK SCR T7 S-T	8
	7469-2414	D-RAD Ti 2.4mm x 14mm LCK SCR T7 S-T	7
	7469-2416	D-RAD Ti 2.4mm x 16mm LCK SCR T7 S-T	7
	7469-2418	D-RAD Ti 2.4mm x 18mm LCK SCR T7 S-T	7
	7469-2420	D-RAD Ti 2.4mm x 20mm LCK SCR T7 S-T	7
	7469-2422	D-RAD Ti 2.4mm x 22mm LCK SCR T7 S-T	4
	7469-2424	D-RAD Ti 2.4mm x 24mm LCK SCR T7 S-T	3
Tray 	7115-8016	D-RAD Screw and Template Tray	1
	7115-8023	D-RAD Screw and Template Tray Lid	1

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