

INTEGRA™

TOTAL WRIST FUSION SYSTEM

Implants – 2.7mm Screws (Non-Sterile)

Reference	Description
286210ND	2.7mm Surfex Screw 10mm long
286212ND	2.7mm Surfex Screw 12mm long
286214ND	2.7mm Surfex Screw 14mm long
286216ND	2.7mm Surfex Screw 16mm long
286218ND	2.7mm Surfex Screw 18mm long
286220ND	2.7mm Surfex Screw 20mm long
286222ND	2.7mm Surfex Screw 22mm long
286224ND	2.7mm Surfex Screw 24mm long
186200ND	2.7mm Surfex Lock-Screw
303210	2.7mm Cortical Screw 10mm long
303212	2.7mm Cortical Screw 12mm long
303214	2.7mm Cortical Screw 14mm long
303216	2.7mm Cortical Screw 16mm long
303218	2.7mm Cortical Screw 18mm long
303220	2.7mm Cortical Screw 20mm long
303222	2.7mm Cortical Screw 22mm long
303224	2.7mm Cortical Screw 24mm long

Implants – 3.5mm Screws (Non-Sterile)

Reference	Description
286312ND	3.5mm Surfex Screw 12mm long
286314ND	3.5mm Surfex Screw 14mm long
286316ND	3.5mm Surfex Screw 16mm long
286318ND	3.5mm Surfex Screw 18mm long
286320ND	3.5mm Surfex Screw 20mm long
286322ND	3.5mm Surfex Screw 22mm long
286324ND	3.5mm Surfex Screw 24mm long
286326ND	3.5mm Surfex Screw 26mm long
286328ND	3.5mm Surfex Screw 28mm long
186300ND	3.5mm Surfex Lock-Screw
303312	3.5mm Cortical Screw 12mm long
303314	3.5mm Cortical Screw 14mm long
303316	3.5mm Cortical Screw 16mm long
303318	3.5mm Cortical Screw 18mm long
303320	3.5mm Cortical Screw 20mm long
303322	3.5mm Cortical Screw 22mm long
303324	3.5mm Cortical Screw 24mm long
303326	3.5mm Cortical Screw 26mm long
303328	3.5mm Cortical Screw 28mm long

Implants – Plates (Non-Sterile)

Reference	Description
303100	Straight Plate
303101	Standard Bend Plate
303102	Short Bend Plate

Instruments

Reference	Description
303400	2.0mm Drill Bit
303401	2.5mm Drill Bit
303402	2.7mm Drill Bit
303403	Double-Ended Cortical Drill Guide for 2.0mm Drill Bit
303404	Double-Ended Cortical Drill Guide for 2.5mm Drill Bit
303405	2.7mm Threaded Surfex Drill Guide for 2.0mm Drill Bit
303406	3.5mm Threaded Surfex Drill Guide for 2.7mm Drill Bit
303407	Depth gauge
303408	Self-Retaining Star Driver
303409	2.5mm Self-Retaining Hex Driver
303410	2.0mm Self-Retaining Hex Driver
303411	Plate Bender - 2.7mm hole
303412	Plate Bender - 3.5mm hole
600731	Screw Forceps
339003ND	Surfix drill guide holder

Tray

Reference	Description
303500	Instrument Case complete - US
30351	Base
303504	Lid
30352	Insert
303503	Screw Caddy



Integra LifeSciences Corporation
 4900 Charlemar Drive, Bldg. A • Cincinnati, OH 45227
 877-444-1114 • 513-533-7979 • 513-271-1915 (Fax)
www.Integra-LS.com

INTEGRA™

TOTAL WRIST FUSION SYSTEM



SURGICAL TECHNIQUE

UPPER
EXTREMITY
SOLUTIONS

 **INTEGRA™**
Extremity Reconstruction

INTEGRA™

TOTAL WRIST FUSION SYSTEM

Description:

The INTEGRA™ Total Wrist Fusion System is designed to provide fixation of the wrist while decreasing soft tissue irritation during total wrist arthrodesis. The system incorporates a combination of Surfix® locking holes and dynamic compression holes to provide the optimal balance of compression and stability.

System Benefits:

- **Decreased Tissue Irritation** – Soft tissue irritation is reduced by both the contoured edges of the plate and the design of the screws, which ensures that they sit flush with the dorsal aspect of the plate.
- **Compression and Stability** – The system incorporates both Surfix locking technology and dynamic compression holes to provide the optimal balance between compression and stability.
- **Efficient and Reliable** – Dedicated instrument system designed to provide precise, reproducible, and efficient implantation.

System Features:

- Contoured edges to reduce soft tissue irritation
- Pre-contoured plates to reduce the need for intraoperative bending
- Built-in plate dorsiflexion to enhance digital function
- Patented Surfix locking technology and dynamic compression holes
- Complete system includes all necessary instruments for implantation

Surgical Technique



As the manufacturer of this device, Integra LifeSciences Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Indications:

The Integra Total Wrist Fusion System is indicated for use in patients with:

- Post-traumatic arthritis of the joints of the wrist
- Rheumatoid wrist deformities requiring restoration
- Complex carpal instability
- Post-septic arthritis of the wrist
- Severe unremitting wrist pain related to motion
- Brachial plexus nerve palsies
- Tumor resection
- Spastic deformities
- Pain and/or loss of function due to osteoarthritis
- Revision of failed partial wrist fusions

Contraindications:

Use of the product is contraindicated in the presence of any of the following:

- Severe tendon, neurological, or muscular deficiencies that would compromise implant function
- Infection; acute or chronic, local or systemic
- Any concomitant disease which may compromise the function of the implant
- Current highly active inflammatory disease of the wrist

See Package Insert for full prescribing information

Step 1 • Surgical Approach

Pre-Operative Considerations

The surgeon should discuss with the patient the alternative treatment options and expectations from surgery. Radiographs are helpful to determine which joints are pathologic and must be eliminated. Discussing the patient's goals while taking into account the condition of the soft tissues and bones, the surgeon can determine the best approach and implant to use. Prophylactic antibiotics are recommended. Fluoroscopic image intensification is suggested to aid in ideal placement of the implant and positioning of the carpus relative to the radius.

Approach

The patient is placed supine on the operating table with the upper extremity extended and pronated to provide access to the dorsum of the wrist. A dorsal longitudinal incision is made over the radius extending approximately from 3cm proximal to Lister's tubercle to the neck of the 3rd metacarpal. (Figure 1)

The 3rd dorsal compartment is opened and the EPL tendon is retracted radially. Lister's tubercle is removed with a rongeur, and cancellous autograft can be harvested. The 2nd and 4th extensor compartments are dissected off the radius sub-periosteally and the interval between the tendons of the 2nd and 3rd dorsal compartments and the 4th dorsal compartment is utilized to expose the dorsal capsule. The capsule is incised longitudinally exposing the dorsal wrist. The 3rd metacarpal periosteum is elevated to facilitate plate placement.



Figure 1

Step 2 • Bone Preparation

Remove any remaining cartilage from the articulations to be fused. Figure 2 illustrates joints that should always be fused during a radiocarpal arthrodesis as well as joints that can optionally be fused based on surgeon preference. A small osteotome can be used to denude the carpals. Fenestrate the subchondral bone with a K-wire or decorticate it with a small burr. Irrigate thoroughly and suction dry. Reduce the carpals on the radius.

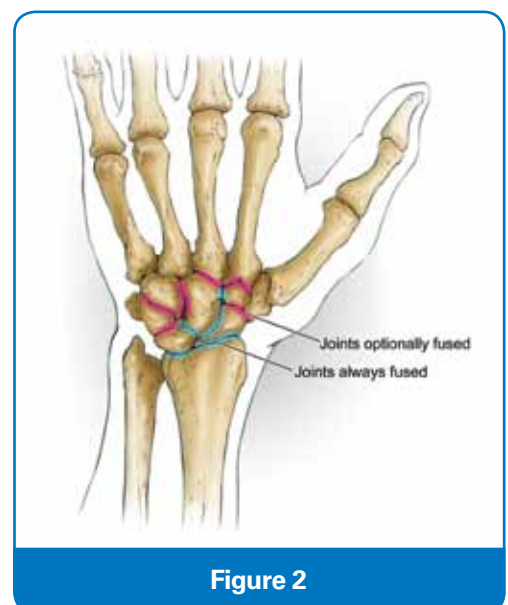
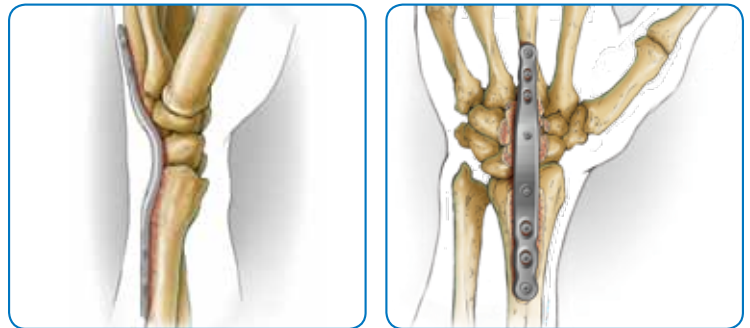


Figure 2

Step 3 • Plate Implantation

The Integra Total Wrist Fusion Plate should be fixed to the third metacarpal and then to the radius. All surfaces to be included in the fusion should be decorticated prior to plate placement. Appropriate screws (2.7mm distal screws and 3.5mm proximal screws) should be placed in the order recommended. Screw holes are numbered in the order of placement. Order of screw placement may depend on patient anatomy and surgeon preference.



Recommended screw sequence for the straight plate:



7 6 5 8 9 1 2 3 4

Recommended screw sequence for the standard or short bend plates:



7 6 5 8 1 2 3 4

Bending Plates (optional)

The straight plate can be bent in up to 35 degrees of extension using the supplied plate benders. Plate benders are threaded into holes 1 and 8. Fully tighten thumb screws on the plate benders. Ensure that the dorsal surface of the plate is adjacent to the “DORSAL” mark on the plate benders.

The plate can only be bent one time. Bent plates should not be placed back in the implant set.

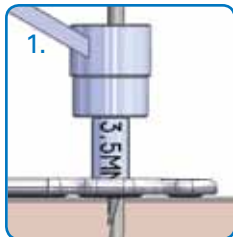
NOTE:

Pre-contoured plates should not be bent.



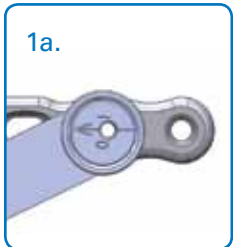
Step 4 • Screw Preparation

HOLE TYPE	Color Code	Drill Bit	Driver
2.7mm Surfex Screw	Black ●	2.0mm	Star Driver
2.7mm Cortical Screw	Yellow ●	2.0mm	2.5mm Hex
3.5mm Surfex Screw	Blue ●	2.7mm	2.0mm Hex
3.5mm Cortical Screw	Green ●	2.5mm	2.5mm Hex



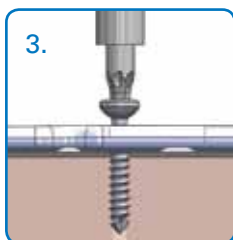
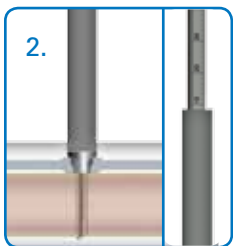
2.7mm Cortical Screw Insertion

- 1) Prepare holes with the 2.0mm drill (303400) through the drill guide (303403).
 - a. If compression is desired, use the eccentric end of the drill guide with the arrow pointing in the direction of compression.
- 2) Measure the necessary screw length using the depth gauge (303407).
- 3) Using the 2.5mm Hex screwdriver (303409), insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate.



3.5mm Cortical Screw Insertion

- 1) Prepare holes with the 2.5mm drill (303401) through the drill guide (303404).
 - a. If compression is desired, use the eccentric end of the drill guide with the arrow pointing in the direction of compression.
- 2) Measure the necessary screw length using the depth gauge (303407).
- 3) Using the 2.5mm Hex screwdriver (303409), insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate.

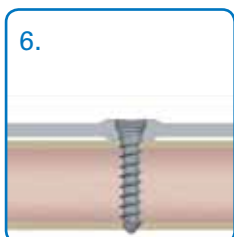
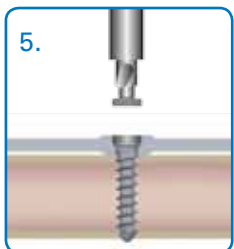
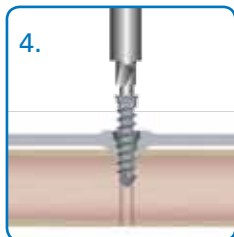
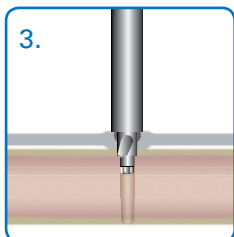
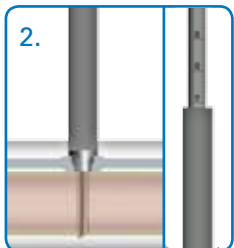
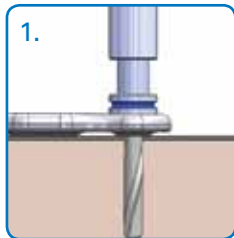


WARNING

Cortical screws should be flush with the surface of the plate except when used in compression. Hand tighten all screws.

All screw holes should be filled in every case.

Standard Surfix locking screw insertion:



2.7mm Surfix Screw Insertion

- 1) Prepare holes with the 2.0mm drill (303400) through the drill guide (303405).
- 2) Remove drill guide and measure the necessary screw length using the depth gauge (303407).
- 3) Chamfer the drill hole with the Star screwdriver (303408). Ensure that the threaded hole is not damaged when performing the chamfering.
- 4) Using the Star screwdriver, insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain coaxiality between the screw and the threaded hole.
- 5) Assemble the lock-screw to the screwdriver. The lock-screw should be inserted after each screw, before preparation and insertion of the subsequent screw. This prevents potential damage to the thread.
- 6) Locking: Fully seat the lock-screw with the screwdriver. The lock-screw should be

3.5mm Surfix Screw Insertion

- 1) Prepare holes with the 2.7mm drill (303402) through the drill guide (303406).
- 2) Remove drill guide and measure the necessary screw length using the depth gauge (303407).
- 3) Chamfer the drill hole with the 2.0mm Hex screwdriver (303410). Ensure that the threaded hole is not damaged when performing the chamfering.
- 4) Using the 2.0mm Hex screwdriver, insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain coaxiality between the screw and the threaded hole.
- 5) Assemble the lock-screw to the screwdriver. The lock-screw should be inserted after each screw, before preparation and insertion of the subsequent screw. This prevents potential damage to the thread.
- 6) Locking: Fully seat the lock-screw with the screwdriver. The lock-screw should be

WARNING

Surfix locking screws must be inserted only into locking holes. The above steps should be completed for each screw before starting preparation of the subsequent screw(s). If not, the axes of the screw and the prepared hole may be misaligned.

Step 5 • Surgical Closure and Postoperative Care

Closure

Pack bone graft into the interstices of the radiocarpal and mid-carpal joints. The capsule is closed with absorbable suture. The extensor retinaculum is repaired and the skin is closed. The EPL tendon may be transposed dorsally based on surgeon preference. Local anesthetic is instilled for post-operative pain management.

Postoperative Care

After the initial period of approximately 2 weeks, the sutures are removed. Therapy is encouraged to maximize range of motion of the remaining joints. Protected activities are maintained until there is evidence of osseous union.

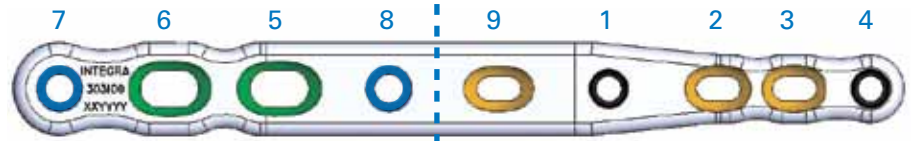
Integra Total Wrist Fusion System - Instrument Tray

1. 2.7mm Surfix Screws
2. 2.7mm Cortical Screws
3. 3.5mm Cortical Screws
4. 3.5mm Surfix Screws
5. Straight Plate
6. Standard Bend Plate
7. Short Bend Plate
8. 2.0mm Drill Bit
9. 2.5mm Drill Bit
10. 2.7mm Drill Bit
11. Double-Ended Cortical Drill Guide for 2.0mm Drill Bit
12. Double-Ended Cortical Drill Guide for 2.5mm Drill Bit
13. 2.7mm Threaded Surfix Drill Guide for 2.0mm Drill Bit
14. 3.5mm Threaded Surfix Drill Guide for 2.7mm Drill Bit
15. Depth gauge
16. Self-Retaining Star Driver
17. 2.5mm Self-Retaining Hex Driver
18. 2.0mm Self-Retaining Hex Driver
19. Plate Bender - 2.7mm hole
20. Plate Bender - 3.5mm hole
21. Screw Forceps
22. Surfix drill guide holder

Straight Plate – 303100

← 3.5mm screws → ← 2.7mm screws →

Recommended Screw Sequence



Drill Guides

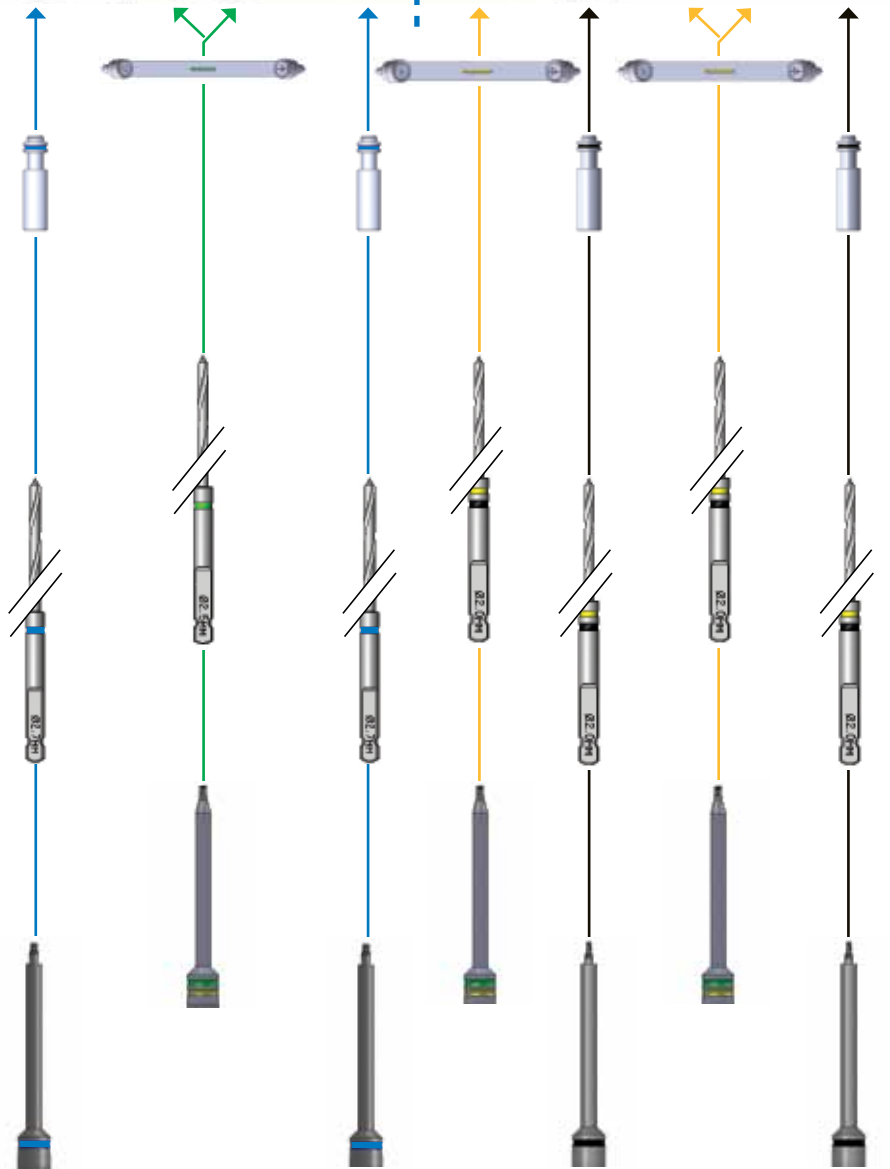
- 303403 – 2.7mm Cortical
- 303404 – 3.5mm Cortical
- 303405 – 2.7mm Surfix®
- 303406 – 3.5mm Surfix®

Drill Bits

- 303400 – 2.0mm
- 303401 – 2.5mm
- 303400 – 2.0mm
- 303402 – 2.7mm

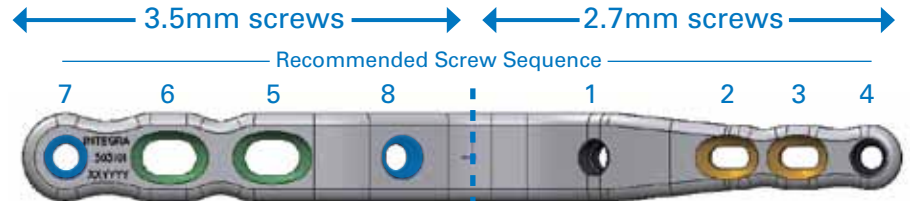
Drivers

- 303409 – 2.5mm Hex
- 303409 – 2.5mm Hex
- 303408 – Star Driver
- 303410 – 2.0mm Hex



Standard Bend Plate – 303101

Short Bend Plate – 303102



Drill Guides

- 303403 – 2.7mm Cortical
- 303404 – 3.5mm Cortical
- 303405 – 2.7mm Surfix®
- 303406 – 3.5mm Surfix®

Drill Bits

- 303400 – 2.0mm
- 303401 – 2.5mm
- 303400 – 2.0mm
- 303402 – 2.7mm

Drivers

- 303409 – 2.5mm Hex
- 303409 – 2.5mm Hex
- 303408 – Star Driver
- 303410 – 2.0mm Hex

