Integra®

Total Wrist Fusion System

SURGICAL TECHNIQUE

INTEGRA™
LIMIT UNCERTAINTY

Products for sale in Europe, Middle-East and Africa only

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As the manufacturer of this device, Integra 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 implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

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 features and benefits

System features	System benefits
Contoured edges.	**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.
Surfix® locking technology. Dynamic compression holes.	The system incorporates both Surfix® locking technology and dynamic compression holes to provide the **optimal balance between compression and stability.**
Pre-contoured plates.	**Save OR time –** Reduce the need for intraoperative bending.
Built-in plate dorsiflexion.	Enhance **digital function.**
Complete system includes all necessary instruments for implantation.	**Efficient and Reliable –** Dedicated instrument system designed to provide precise, reproducible, and efficient implantation.

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.

Note
See package insert for full prescribing information.

Plates

Straight Plate - 303100S
Stainless steel
Sterile

Standard Bend Plate - 303101S
Stainless steel
Sterile

Short Bend Plate - 303102S
Stainless steel
Sterile

Screws

Screw (diameter)	3.5 mm Surfix® Screw	3.5 mm Cortical Screw	2.7 mm Cortical Screw	2.7 mm Surfix® Screw
Coulour Code				
Material	stainless steel	stainless steel	stainless steel	stainless steel
Sterile	✔	✔	✔	✔
Length	12 mm to 28 mm	12 mm to 28 mm	10 mm to 24 mm	10 mm to 24 mm
Reference	286312SND to 286328SND	303212CS to 303228CS	303210CS to 303224CS	286210SND to 286224SND
Driver	**303410 -** 2.0 mm Hex	**303409 -** 2.5 mm Hex	**303409 -** 2.5 mm Hex	**303408 -** T7 Torx

Recommended screw sequence for Standard Bend Plate (303101S) & Short Bend Plate (303102S)

278002S
DPR Burr straight
dia 2.0 mm
L15 mm

278005S
DPR Burr straight
dia 1.9 mm
L10 mm

Surgical Technique

1. Surgical approach

1-1

Pre-Operative considerations

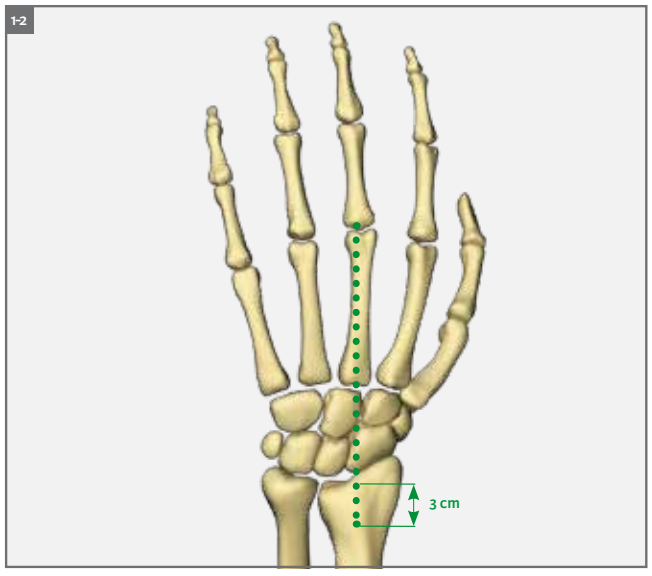
The surgeon should discuss with the patient the alternative treatment options and expectations from surgery. Radiographs are helpful to determine which joints are pathologic and must be eliminated. Discussing the patients goals while taking into account the condition of the soft tissues and bones, the 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.

1-2

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 3 cm proximal to Lister's tubercle to the neck of the 3rd metacarpal.

The 3rd dorsal compartment is opened and the EPL (Extensor Pollicis Longus) 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.

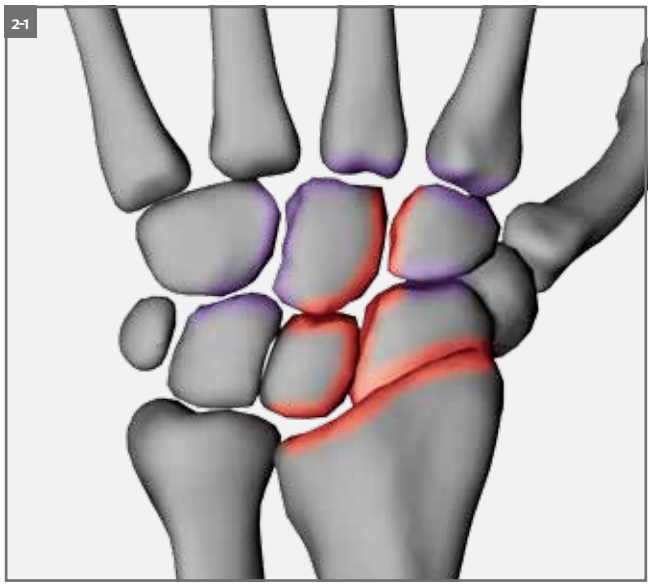


• • • Incision

2. Bone preparation

2-1

Remove any remaining cartilage from the articulations to be fused. The figure below illustrates joints which should always be fused during a radiocarpal arthrodesis as well as joints which can optionally be fused based on surgeon preference. A small osteotome can be used to denude the carpals.



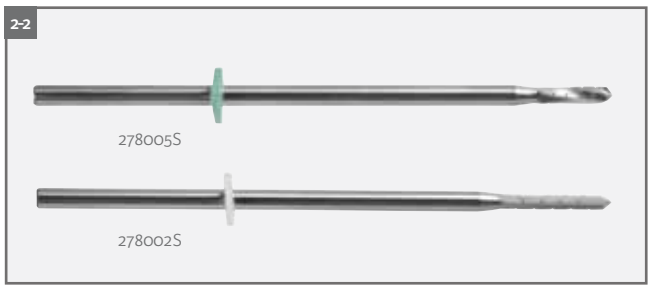
Joints optionally fused Joints always fused

2-2

Fenestrate the subchondral bone with a K-wire or remove it with a small DPR burr. Irrigate thoroughly and suction dry. Reduce the carpals on the radius.

In order to maximize bone fusion you can use an autograft (Eg illiac crest) or Integra OS™ *(osteoconductive scaffold) to maximize bone healing.

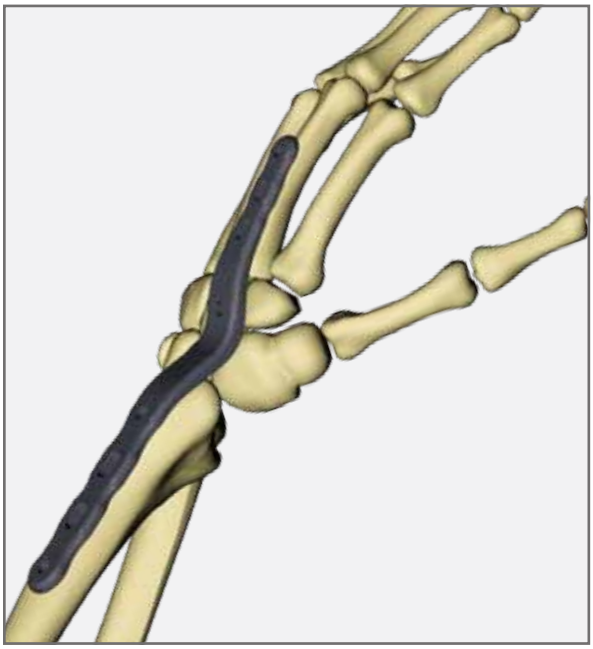
* Availability of these products might vary from a given country or region to another. Integra OS™ is manufactured by Integra LifeSciences Corporation, Plainsboro, NJ08536, USA. Integra OS™ EC Rep is Integra Lifesciences Services France S.A.S., 69800 Saint Priest, France.



3. Trial positioning

3-1 Trials are used to determine the appropriate implant shape.

Caution
Do not implant trials instead of definitive implant!



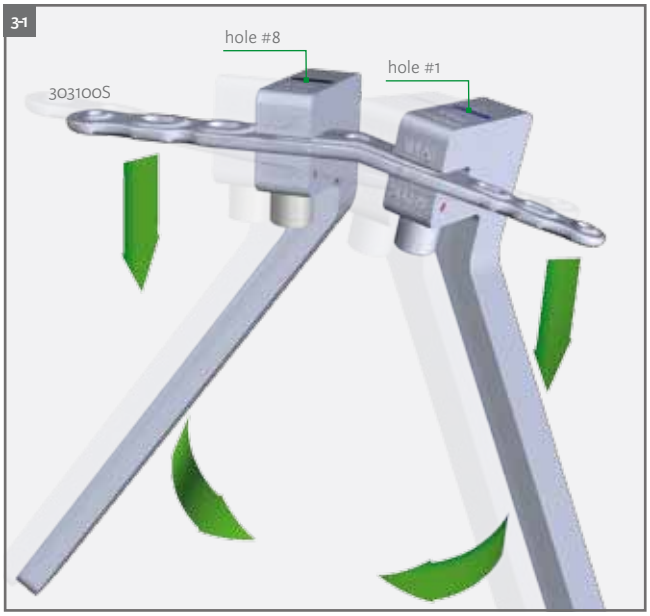
The 1st hole has to be positioned on the capitate.
The 2nd, 3rd and 4th on the metatarse.
All the other holes will be positioned on the radius.

Bending Plates (optional)

Caution
Only the straight definitve implant can be bent.

If the two bend plates do not well fit the wrist, the definitive 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.

3-1



303403
Double-Ended Drill Guide for 2.0 mm Drill Bit (Yellow)

303404
Double-Ended Drill Guide for 2.5 mm Drill Bit (Green)

303405
Threaded Drill Guide for 2.7 mm Drill Bit (Black)

303406
Threaded Drill Guide for 2.0 mm Drill Bit (Blue)

303400
2.0 mm Drill Bit (Yellow and Black)
303401
2.5 mm Drill Bit (Green)
303402
2.7 mm Drill Bit (Blue)

303409
303410
Hex screwdriver

4. Requirements

4-1 Recommended screw sequence

The Integra® Total Wrist Fusion Plate should be fixed to the 3rd metacarpal and then to the radius.
All surfaces to be included in the fusion should be decorticated prior to plate placement.
Appropriate screws (2.7 mm distal screws and 3.5 mm 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.

Note
Recommended screw sequence for the straight plate:

Note
Recommended screw sequence for the standard or short bend plates:

4-2 Colour code

Colours				
Drill guides	**303406 -** 3.5 mm Surfix®	**303404 -** 3.5 mm Double-Ended	**303403 -** 2.7 mm Double-Ended	**303405 -** 2.7 mm Surfix®
Drill bits	**303402 -** Drill 2.7 mm	**303401 -** Drill 2.5 mm	**303400 -** Drill 2.0 mm	**303400 -** Drill 2.0 mm
Drivers	**303410 -** 2.0 mm Hex	**303409 -** 2.5 mm Hex	**303409 -** 2.5 mm Hex	**303408 -** T7 Torx

303400
2.0 mm drill bit
(Black and Yellow)
303402
2.7 mm drill bit
(Blue)

303405
Threaded Drill
Guide for 2.0 mm
Drill Bit (Black)
303406
Threaded Drill
Guide for 2.7 mm
Drill Bit (Blue)

303410
2.0 mm
Self-Retaining
Hex Driver
(Blue)

303408
Self-Retaining
Torx Driver
(Black)

303407
Depth Gauge

4-3 Surfix® screw insertion

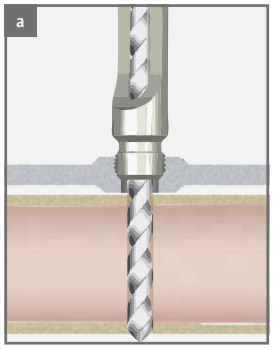
Surfix® Screw Insertion (2.7 mm)

Surfix® Screw Insertion (3.5 mm)

a

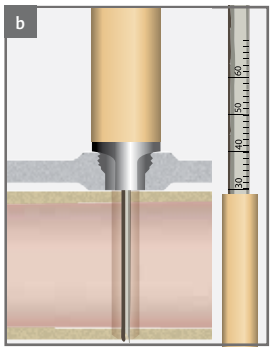
Prepare holes with the 2.0 mm drill (303400 = Black & Yellow) through the drill guide (303405 = Black).

Prepare holes with the 2.7 mm drill (303402 = Blue) through the drill guide (303406 = Blue).



b

Measure the necessary screw length using the depth gauge (303407).

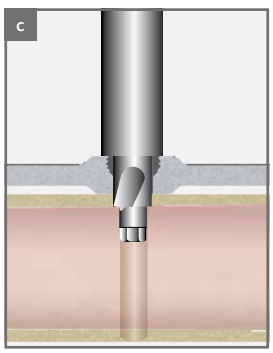


c

Chamfer the drill hole with the Star screwdriver (303408 = Black).

Chamfer the drill hole with the 2.0 mm Hex screwdriver (303410 = Blue).

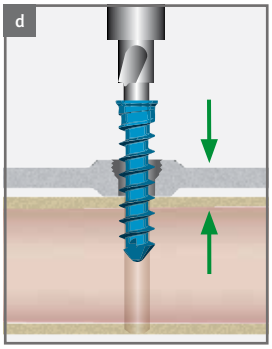
Ensure that the threaded hole is not damaged when performing the chamfering.



d

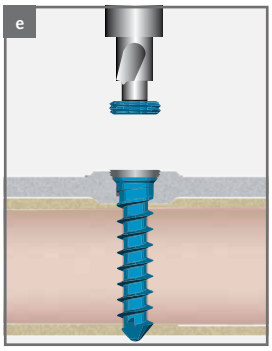
Using the Star screwdriver (303408 = Black), insert the screw into the prepared hole until the plate is at the desired position relative to the bone.

Using the 2.0 mm Hex screwdriver (303410 = Blue), 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 co-axiality between the screw and the threaded hole.



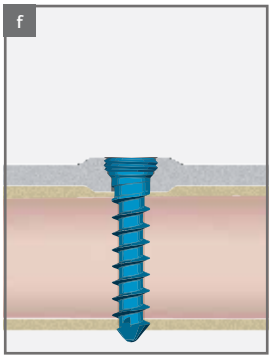
e

Assemble the lock-screw to the screwdriver. The lock-screw should be inserted after each screw, and before preparation and insertion of the subsequent screw. This prevents potential damage to the thread.



f

Locking: Fully seat the lock-screw with the screwdriver. The lock-screw should be flush with the top of the plate when it is fully inserted.



Caution
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.

303403
Double-Ended Drill Guide for 2.0 mm Drill Bit (Yellow)

303404
Double-Ended Drill Guide for 2.5 mm Drill Bit (Green)

303400
2.0 mm Drill Bit (Yellow and Black)
303401
2.5 mm Drill Bit (Green)

303407
Depth Gauge

303409
2.5 mm Self-Retaining Hex Driver (Green and Yellow)

4-4 Cortical screw insertion

Cortical Screw Insertion (2.7 mm)

Cortical Screw Insertion (3.5 mm)

Step 1 Prepare holes with the 2.0 mm drill (303400 = Yellow and Black) through the drill guide (303403 = Yellow). Prepare holes with the 2.5 mm drill (303401 = Green) through the drill guide (303404 = Green).

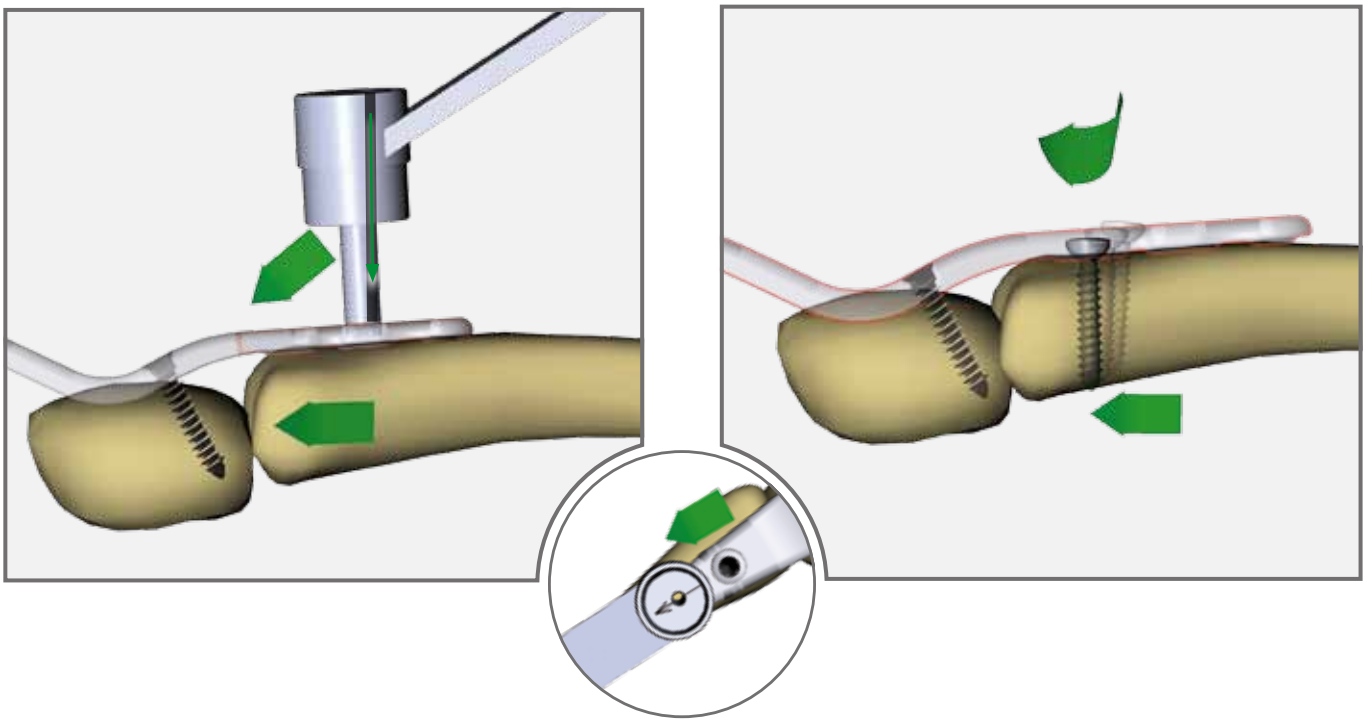
If compression is desired, use the eccentric end of the drill guide with the arrow pointing in the direction of compression. (Explanation with the 3 pictures below).

Step 2 Measure the necessary screw length using the depth gauge (303407).

Step 3 Using the 2.5 mm Hex screwdriver (303409 = Green and Yellow), 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.

Caution
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.

Thanks to the eccentric drill guide and the shape of the cortical holes, cortical screws will add compression between the two bones. The direction of the arrow indicates the direction of the compression.



303405
Threaded Drill Guide for 2.0 mm Drill Bit
303406
Threaded Drill Guide for 2.5 mm Drill Bit

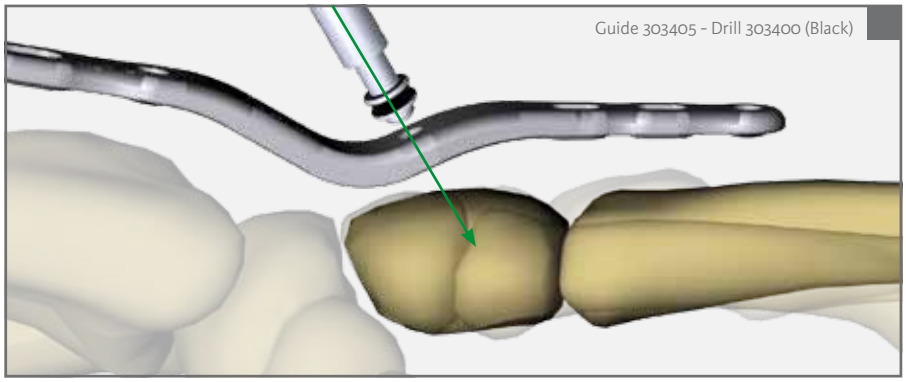
303403
Double-Ended Drill Guide for 2.0 mm Drill Bit
303404
Double-Ended Drill Guide for 2.5 mm Drill Bit

303400
2.0 mm drill bit
303401
2.5 mm drill bit
303402
2.7 mm drill bit

5. Plate implantation

5-1 Carpo Metacarpal Fusion

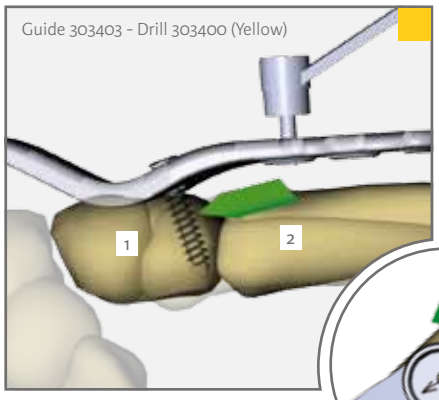
Capitate fixation screw: Surfix® screw

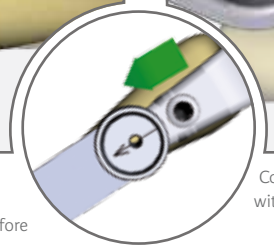


Positioning of the plate thanks to the fisrt 2.7 mm Surfix® screw.

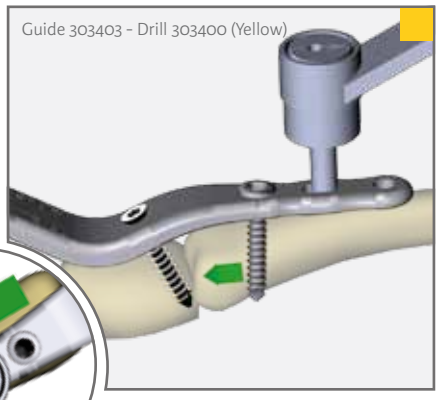
Note
The screws are recommended to be implanted in the very order it is recommended, from 1 to 9 for the straight plate, from 1 to 8 for the bent one.

5-2 Metacarpal screws

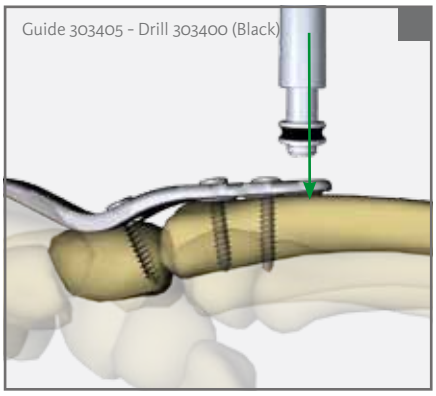




Compression capitate + metacarpus with 2.7 mm cortical screw.
The compression is manually achieved before drilling the second hole.
Arrow on the drill guide shows the direction of the compression.

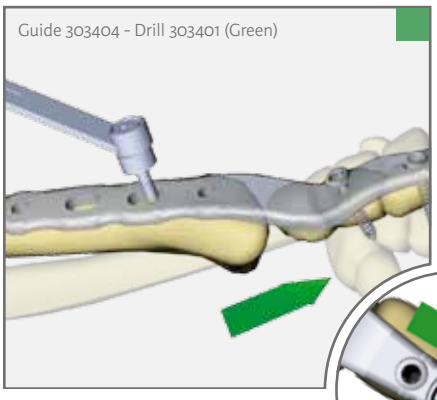


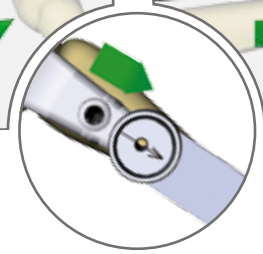
Compression capitate + metacarpus with 2nd 2.7 mm cortical screw.



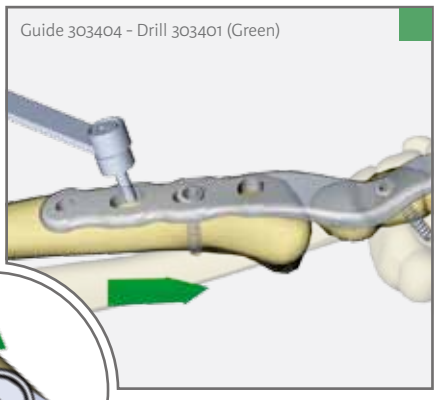
Lock of the compression with 2.7 mm Surfix® screw.

5-3 Radio Carpal Fusion

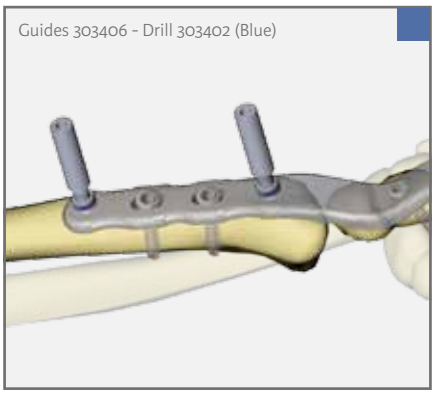




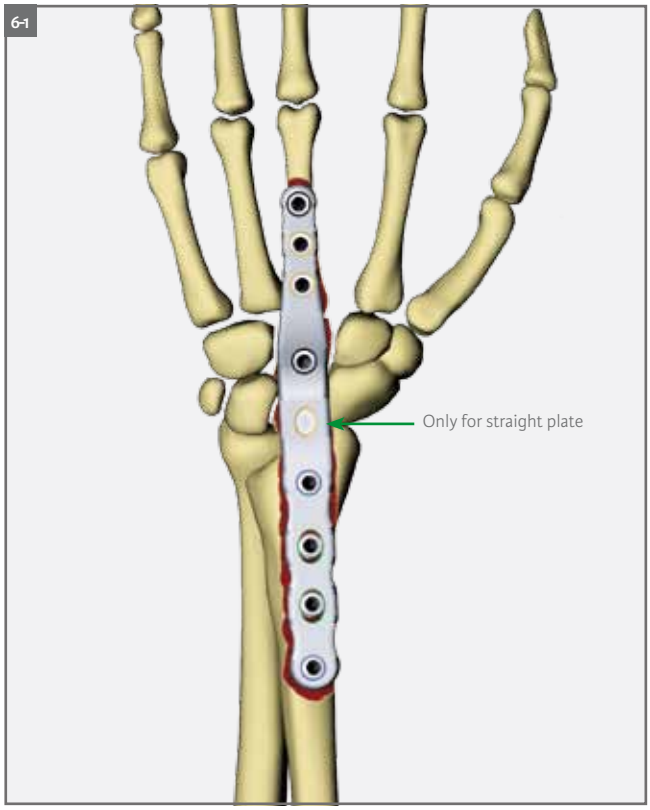
Compression radius + lunate with 3.5 mm cortical screw.
The compression is manually achieved before drilling the fifth hole.



Compression radius + lunate with 2nd 3.5 mm cortical screw.



Lock of the compression with two 3.5 mm Surfix® screws.



6. Surgical Closure and Postoperative Care

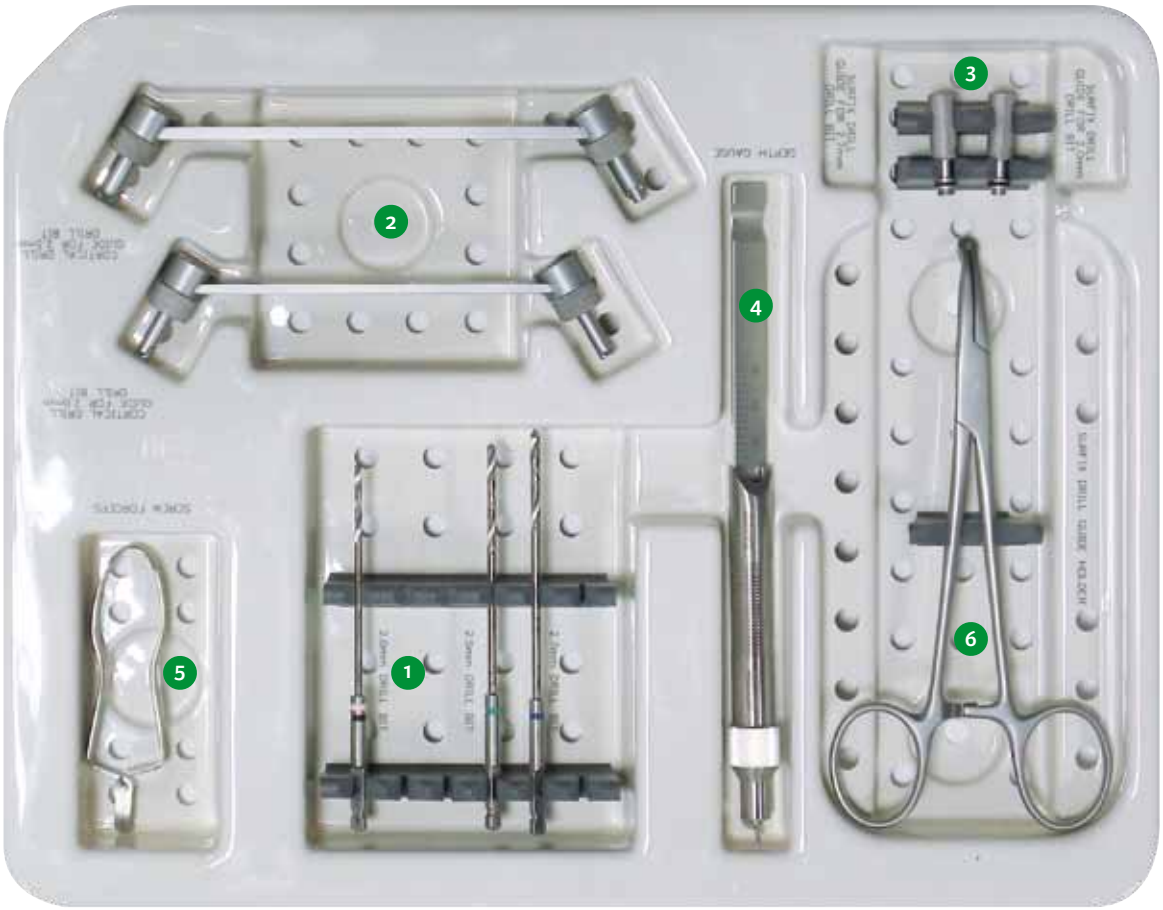
6-1 Closure

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.

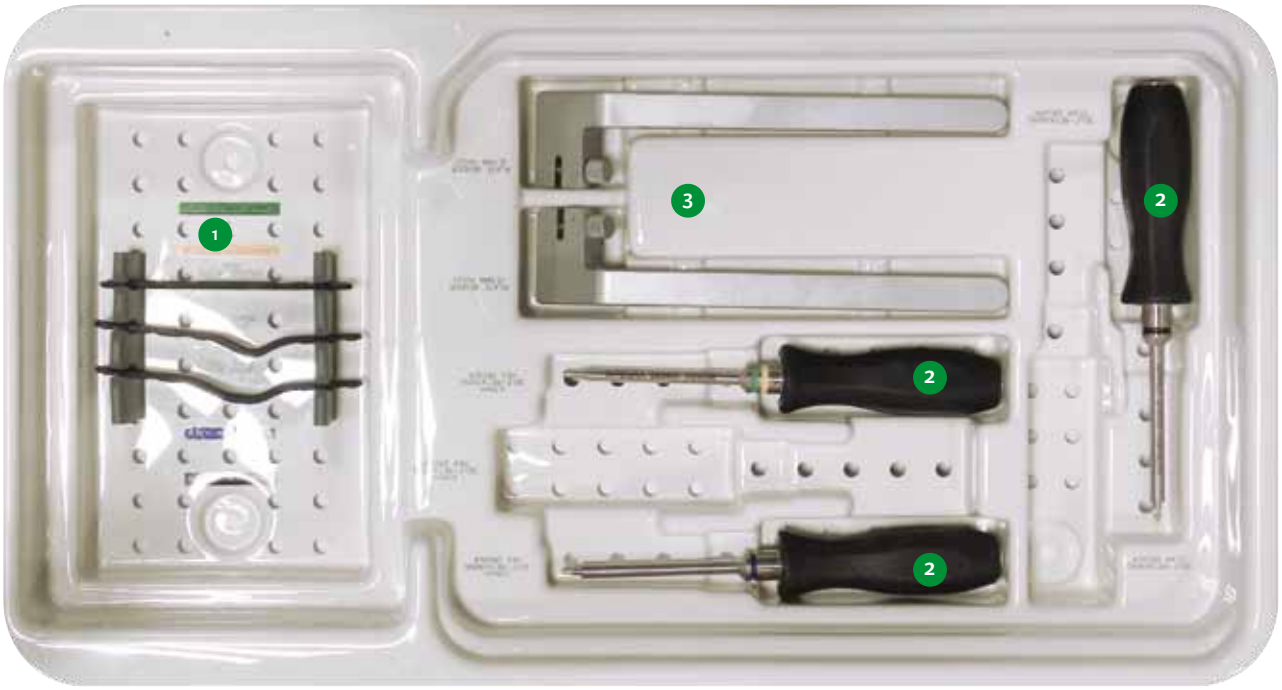
6-2 Postoperative Care

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 - Instruments tray



#	Designation
1	2.0 mm Drill Bit
1	2.5 mm Drill Bit
1	2.7 mm Drill Bit
2	Double-Ended Cortical Drill Guide for 2.0 mm Drill Bit
2	Double-Ended Cortical Drill Guide for 2.5 mm Drill Bit
3	Threaded Drill Guide for 2.0 mm Drill Bit
3	Threaded Drill Guide for 2.7 mm Drill Bit
4	Depth gauge
5	Screw Forceps
6	Surfix® drill guide holder



#	Designation
1	Straight Plate Trial
1	Standard Bend Plate Trial
1	Short Bend Plate Trial
2	Self-Retaining Torx Driver
2	2.5 mm Self-Retaining Hex Driver
2	2.0 mm Self-Retaining Hex Driver
3	Plate Bender - 2.7 mm hole
3	Plate Bender - 3.5 mm hole

References

Implants – 2.7 mm stainless steel Screws (Sterile)

Reference	Description
2.7 mm Surfix® Screws**	
286210S	2.7 mm Surfix® Screw 10 mm long and 2.7 mm Surfix® Locking screw
286212S	2.7 mm Surfix® Screw 12 mm long and 2.7 mm Surfix® Locking screw
286214S	2.7 mm Surfix® Screw 14 mm long and 2.7 mm Surfix® Locking screw
286216S	2.7 mm Surfix® Screw 16 mm long and 2.7 mm Surfix® Locking screw
286218S	2.7 mm Surfix® Screw 18 mm long and 2.7 mm Surfix® Locking screw
286220S	2.7 mm Surfix® Screw 20 mm long and 2.7 mm Surfix® Locking screw
286222S	2.7 mm Surfix® Screw 22 mm long and 2.7 mm Surfix® Locking screw
286224S	2.7 mm Surfix® Screw 24 mm long and 2.7 mm Surfix® Locking screw
186200S	2.7 mm Surfix® Locking screw

Implants – 2.7 mm stainless steel Screws (Sterile)

Reference	Description
2.7 mm Cortical Screws*	
303210CS	2.7 mm Cortical Screw 10 mm long Sterile
303212CS	2.7 mm Cortical Screw 12 mm long Sterile
303214CS	2.7 mm Cortical Screw 14 mm long Sterile
303216CS	2.7 mm Cortical Screw 16 mm long Sterile
303218CS	2.7 mm Cortical Screw 18 mm long Sterile
303220CS	2.7 mm Cortical Screw 20 mm long Sterile
303222CS	2.7 mm Cortical Screw 22 mm long Sterile
303224CS	2.7 mm Cortical Screw 24 mm long Sterile

Implants – 3.5 mm stainless steel Screws (Sterile)

Reference	Description
3.5 mm Surfix® Screws**	
286312S	3.5 mm Surfix® Screw 12 mm long and 3.5 mm Surfix® Locking screw
286314S	3.5 mm Surfix® Screw 14 mm long and 3.5 mm Surfix® Locking screw
286316S	3.5 mm Surfix® Screw 16 mm long and 3.5 mm Surfix® Locking screw
286318S	3.5 mm Surfix® Screw 18 mm long and 3.5 mm Surfix® Locking screw
286320S	3.5 mm Surfix® Screw 20 mm long and 3.5 mm Surfix® Locking screw
286322S	3.5 mm Surfix® Screw 22 mm long and 3.5 mm Surfix® Locking screw
286324S	3.5 mm Surfix® Screw 24 mm long and 3.5 mm Surfix® Locking screw
286326S	3.5 mm Surfix® Screw 26 mm long and 3.5 mm Surfix® Locking screw
286328S	3.5 mm Surfix® Screw 28 mm long and 3.5 mm Surfix® Locking screw
186300S	3.5 mm Surfix® Lock-Screw

Implants – 3.5 mm stainless steel Screws (Sterile)

Reference	Description
3.5 mm Cortical Screws*	
303312CS	3.5 mm Cortical Screw 12 mm long Sterile
303314CS	3.5 mm Cortical Screw 14 mm long Sterile
303316CS	3.5 mm Cortical Screw 16 mm long Sterile
303318CS	3.5 mm Cortical Screw 18 mm long Sterile
303320CS	3.5 mm Cortical Screw 20 mm long Sterile
303322CS	3.5 mm Cortical Screw 22 mm long Sterile
303324CS	3.5 mm Cortical Screw 24 mm long Sterile
303326CS	3.5 mm Cortical Screw 26 mm long Sterile
303328CS	3.5 mm Cortical Screw 28 mm long Sterile

* Manufactured by Integra LifeSciences Corporation, Cincinnati, OH45227, USA . EC Rep is Integra Lifesciences Services France S.A.S., 69800 Saint Priest, France.
** Manufactured by Newdeal SAS, 69800 Saint Priest, France

Integra™
Integra® Total Wrist Fusion System

Implants – Stainless steel Plates (Sterile)*

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

Tray*

Reference	Description
303510	Instrument Case Complete - EMEA

DPR Burr (Optional)**

Reference	Description
278002S	DPR burr straight dia 2.0 mm L15 mm
278005S	DPR burr straight dia 2.0 mm L10 mm

Integra OS™***

Reference	Description
IOS10155ITL	Integra OS™ Putty 5cc
IOS10125ITL	Integra OS™ Putty 2.5cc

Instruments*

Reference	Description
303400	2.0 mm Drill Bit
303401	2.5 mm Drill Bit
303402	2.7 mm Drill Bit
303403	Double-Ended Drill Guide for 2.0 mm Drill Bit
303404	Double-Ended Drill Guide for 2.5 mm Drill Bit
303405	Threaded Drill Guide for 2.0 mm Drill Bit
303406	Threaded Drill Guide for 2.7 mm Drill Bit
303407	Depth gauge
303408	Self-Retaining Torx Driver
303409	2.5 mm Self-Retaining Hex Driver
303410	2.0 mm Self-Retaining Hex Driver
303411	Plate Bender - (2.7 mm hole)
303412	Plate Bender - (3.5 mm hole)
303450	Straight Plate Trial
303451	Standard Bend Plate Trial
303452	Short Bend Plate Trial
600731	Screw forceps

Instruments**

Reference	Description
339003	Surfix® drill guide holder

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** Manufactured by Newdeal SAS, 69800 Saint Priest, France
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