

## **Surgical Dynamics\*** **RAY TFC\* and Ray TFC Unite\* Device**

### **Device Description**

#### **Ray TFC\* Device**

The Ray TFC\* Device is a hollow threaded cylinder with holes. It is available in ten sizes, with 5 diameters (12 mm, 14 mm, 16 mm, 18 mm, and 20 mm) and 2 lengths (21 mm or 26 mm).

#### **Ray TFC Unite\* Device**

The Ray TFC Unite\* Device is a hollow threaded cylinder with holes. The Ray TFC Unite\* Device also includes two lateral arcs, which allow closer approximation of two (2) devices in the intervertebral space. It is available in ten sizes, with 5 diameters (12 mm, 14 mm, 16 mm, 18 mm, and 20 mm) and 2 lengths (21 mm or 26 mm).

Both the Ray TFC\* Device and the Ray TFC Unite\* Device are composed of Titanium 6Al-4V (extra low interstitial) alloy, which conforms to the American Society for Testing and Materials (ASTM) F136-92. The Ray TFC\* and Ray TFC Unite\* devices are used with anterior and posterior end caps (use of the anterior end cap in ALIF procedures is optional), which are available in corresponding diameters of 12 mm, 14 mm, 16 mm, 18 mm and 20 mm. The end caps are composed of ultra-high-molecular weight polyethylene (UHMWPE) which conforms to ASTM F648-84.

The Ray TFC\* and Ray TFC Unite\* devices and endcaps are implanted using a set of stainless steel instruments whose material conforms to ASTM F899-94. Refer to the Surgical Technique Manual or the individual instrument package insert for a full description of these instruments and their cleaning and sterilization instructions.

### **Indications**

The Ray TFC\* and Ray TFC Unite\* devices are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels for L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The Ray TFC\* and Ray TFC Unite\* devices are to be implanted via either an open posterior approach or an open anterior approach. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six months of nonoperative therapy.

### **Contraindications**

The Ray TFC\* and Ray TFC Unite\* devices should not be implanted in patients with an active infection at the operative site.

### **Warnings**

Implantation of a single cage per involved level is not recommended. The implantation of a single cage has been associated with cage fracture.

## **Precautions**

- Prior to use, the physician should be trained in the surgical procedure recommended for the use of this device.
- Safety and effectiveness have not been established for patients with the following conditions: previous fusion attempt at the involved level(s), spondylolisthesis greater than Grade I, three or more levels to be fused, concomitant conditions requiring steroids, systemic or terminal illness, active drug abuse, gross obesity, severe osteoporotic conditions and pregnancy.
- The Ray TFC\* and Ray TFC Unite\* devices and end caps are packaged sterile. Do not use if the outer package is opened or damaged. Single use only. Do not reuse. Do not resterilize.
- Instruments for implantation of the Ray TFC\* and Ray TFC Unite\* devices and end caps are provided NONSTERILE and must be sterilized prior to use.
- Avoid exposure to freezing temperatures, as this could adversely effect the polyethylene end caps.

## **Adverse Events**

Two clinical studies using the Ray TFC\* device were completed. The first was a 2-year, multicenter clinical study in which 236 patients underwent surgery, all of which were implanted with the Ray TFC\* device via an open posterior approach. The second was a 6-month, multicenter clinical study in which 225 patients underwent surgery, of which 224 patients were implanted with the Ray TFC\* device via an open anterior approach. The rates of the complications reported in each study are provided below.

## **Operative Complications**

Operative complications for implantation of the cages using an open PLIF and an open ALIF surgical approach are presented in Table 1 below. The rates presented are the number of a particular complication divided by the total number of patients in the study (N).

**TABLE 1 Operative Complications**

<b>Complication</b>	<b>PLIF Rate N=236</b>	<b>ALIF Rate N=225<sup>2</sup></b>
Dural Tear	9.3% (22/236)	0
Instrument Malfunctions	5.1% (12/236) <sup>1</sup>	0
Improper Device Placement	4.2% (10/236)	0
Hemorrhage	2.1% (5/236)	1.8% (4/225)
Neural Structure Injury	0.8% (2/236)	0
Incorrect Level	0.4% (1/236)	0
Vascular Bypass	0	0.4% (1/225)
Pinpoint Laceration of Vena Cava	0	0.4% (1/225)
Incidental Opening of Peritoneum	0	0.4% (1/225)
Supplemental Fixation <sup>3</sup>	0	0.4% (1/225)

<sup>1</sup>The instruments have since been redesigned with the intent to simplify their use and to address the reported malfunctions.

<sup>2</sup>Total number of patients at operative time point was 225 for the ALIF study.

<sup>3</sup>Supplemental Fixation is a procedure in which additional instrumentation not under study in the protocol is implanted.

### **Postoperative Complications**

Postoperative complications are presented below in Tables 2 and 3. These complications have been recorded through 24 months for PLIF and 6 months for ALIF-Open. The rates presented are the number of patients with a particular complication divided by the total number of patients in the study (N).

**TABLE 2 Post-Operative Complications**

Complication	PLIF N=236 0-2 years (cumulative # of events)	ALIF N=224 0-6 months (cumulative # of events)	ALIF Lit Control N=varied 0-27 years (# articles out of 31 reporting complication)
CSF Leak/Dural Tear	1.27% (3)	0.45% (1)	Not Reported
Death (unrelated to device/procedure)	0.42% (1)	0.45% (1)	0.4% - 3.1% <sup>o</sup> (3)
Device Fracture/Collapse/Failure	0.42% (1)	0.45% (1)	4.6% - 5.7% (2)
Dislocation of Device	0	0.45% (1)	0.4% - 2.9% (5)
Dislocation of Device End Cap	0	0	Not Reported
Donor Site Infection	0	0.45% (1)	9.3% (1)
Donor Site Pain	2.12% (5)	2.23% (5)	0.7% - 37.1% (5)
Embolism	0	0	0.9% - 6.1% (6)
Epidural Fibrosis	0.42% (1)	0	Not Reported
Hematoma	1.27% (3)	1.34% (3)	2.8% (1)
Hemorrhage	0	1.34% (3)	1.0% (1)
Hernia	0	1.34% (3)	0.5% - 3.7% (3)
Ileus/Paralytic Ileus	0.42% (1)	0.89% (2)	2.0% - 8.2% (7)
Neurological Deficit/Sensory Disturbance/Numbness	4.66% (11)	1.34% (3)	2.0% - 32.1% (10)
(Unresolved) Neurological Deficit at Two Years	2.54% (6)	N/A	Not Reported
(Unresolved) Pain at Two Years	3.0% (7)	N/A	Not Reported
Pain Other than Operative Level	6.36% (15)	5.8% (13)	19.1% - 77.9% (7)
Pain Related to Operative Level	6.78% (16)	10.27% (23)	13.9% - 107.5% <sup>1</sup> (19)
Peritoneal Perforation	0	1.34% (3)	Not Reported
Premature Ejaculation	0.42% (1)	0	Not Reported
Pneumonia	0	0.45% (1)	1.0% - 2.8% (2)
Pneumothorax	0.42% (1)	0	Not Reported
Prolonged Bowel Obstruction	0	0.45% (1)	Not Reported
Pseudoarthrosis	1.27% (3)	0.45% (1)	Not Reported
Retrograde Ejaculation/Loss of Ejaculation	0	0	1.0% - 3.0% (8)
Surgical Intervention	3.39% (8) <sup>1</sup>	5.8% (13) <sup>1</sup>	1.9% - 25.9% (10)
Thrombosis/Thrombophlebitis	0	1.79% (4)	2.2% - 11.2% (10)
Urinary Infection	0	0	
Urinary Retention	0.85% (2)	1.34% (3)	2.8% - 27.8% (6)
Urological- other	0	1.34% (3)	1.0% (1)
Vessel Damage	0	1.34% (3)	1.4% - 2.2% (2)
Weakness	0	0	2.4% (1)
Wound Dehiscence	0	1.79% (4)	2.8% (1)
Wound Infection (superficial/deep)	2.54% (6)	2.68% (6)	1.9% - 5.3% (8)
Other	0	8.93% (20) <sup>3</sup>	0.4% - 6.0% <sup>4</sup> (11)

<sup>1</sup> See Table 3 below

<sup>2</sup> Includes 0 revisions, 7 removals, 84 reoperations, and 0 supplemental fixations.

<sup>3</sup> Includes 1 IV site infection/LL lobe atelectasi, 1 incisional hernia, 1 unresponsive PCA, 1 MVA, 1 kidney cyst, 1 sensory loss left leg/geni nerve, 1 resting tachycardia, 1 chest pain, 1 confusion, 1 seroma, 1 leg swelling, 1 rectal bleeding, 1 failed back syndrome, 1 non-displaced FX R ant sup ILI, 1 vomiting, 1 gastritis, 1 possible muscle spasm, 1 bone fragment, 1 depression, 1 disc herniation, 1 kidney stones, 1 paraspinous spasm

<sup>4</sup>Includes 1 wrong level, 2 heart attacks, 2 arachnoiditis, 4 atelectasis, 1 diskitis, 6 graft instability/resorption, 1 retained sponge, 9 serum hepatitis, 5 edema, 3 genital dysfunction/impotence, 14 bed sores, 1 keloid scar, 2 recurrent disc herniation

<sup>5</sup>Excludes Supplemental Fixation reported in Table 1

<sup>6</sup>Reported Range of Complication in ALIF literature.

<sup>7</sup>Total number of events is cumulative at any given time point, therefore the rate exceeded 100%.

**Table 3 Subsequent Surgical Interventions**

Subsequent Surgical Intervention	PLIF N=236 over 2 years (cumulative events)	ALIF N=224 over 6 months (cumulative events)
Removals <sup>9</sup>	0.4% (1)	0.4%(1)
Revisions <sup>10</sup>	1.3% (3)	0%
Reoperations <sup>11</sup>	0%	2.2%(5)
Supplemental Fixations <sup>12</sup>	1.7% (4)	3.1%(7)

<sup>9</sup>N excludes the one supplemental fixation patient included in Table 1.

<sup>9</sup>Removal is a procedure where *all* of the original system configuration is removed with or without replacement

<sup>10</sup> Revision is a procedure that adjusts or in any way modifies or removes *part* of the original implant configuration, with or without replacement of a component. A revision may also include adjusting the position of the original configuration.

<sup>11</sup> Reoperation is any surgical procedure at the involved level(s) that does not involve removal, modification, or addition of any components to the system

<sup>12</sup>Supplemental Fixation is a procedure in which additional instrumentation not under study in the protocol is implanted.

## Clinical Results

The following are clinical results of the same multi-center studies presented above. The success rates are for overall success as well as for each of the four major individual measures of success. Overall success was defined as fusion at the involved level(s); improvement in pain; maintenance or improvement in function; and maintenance or improvement in muscle strength. Note that actual number of patients with data available differs slightly for each success criteria based on study follow-up.

It should be noted that fusion is defined as follows: no motion on superimposition of flexion and extension x-rays, as corroborated by the absence of halo around the implant, the absence of bone sclerosis, and the maintenance or increase in bone density within the device.

**TABLE 4 Summary of Clinical Results**

SUCCESS PARAMETERS	PLIF At 2 Years	
OVERALL SUCCESS (MET ALL 4 BELOW)	128/199	64%
FUSION RATE	183/200	92%
MUSCLE STRENGTH MAINTENANCE OR IMPROVEMENT	197/208	95%
FUNCTION MAINTENANCE OR IMPROVEMENT	200/209	96%
PAIN IMPROVEMENT	158/209	76%

SUCCESS PARAMETERS	ALIF <sup>1</sup> At 6 Months		PLIF <sup>1</sup> At 6 Months	
OVERALL SUCCESS (MET FUSION & CLINICAL OUTCOMES)	109/202**	54%	108/223**	48%
FUSION RATE	165/202	82%	163/223	73%
3 CLINICAL OUTCOMES <sup>2</sup>	126/202	62%	141/223	63%

<sup>1</sup> 202 patients in the ALIF study and 223 patients in the PLIF study were available for analysis at the 6-month follow-up. Patients who were present for the follow-up, but who did not receive assessments of fusion, or clinical outcomes, or both were reported as failures in this table.

<sup>2</sup> 3 Clinical Outcomes include muscle strength maintenance or improvement, function maintenance or improvement, and pain improvement.

From the PLIF clinical study, the following statistical differences were observed up to or at the 2-year time point:

- Younger patients had lower levels of pain and higher levels of function than older patients.
- Nonsmokers had lower levels of pain and higher levels of function than smokers.
- Patients with baseline disc herniation had lower levels of pain than those without baseline disc herniation.
- Older patients with L5-S1 involvement had higher levels of pain than older patients with other levels of involvement. In younger patients, there was no significant effect on pain based on level of involvement.
- Patients who had lower baseline function scores showed lower levels of function through the study than those with higher baseline scores.
- Older patients with L5-S1 involvement had lower levels of function than older patients with other levels of involvement. Additionally, older patients with lower baseline function scores had lower levels of function than older patients with higher baseline function scores. In younger patients, there was no significant effect on function based on level of involvement or baseline function score.

**CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician with appropriate training or experience.**

**Device Retrieval Efforts**

Should it be necessary to remove a Ray TFC\* or Ray TFC Unite\* device, please call Surgical Dynamics, Inc. at the number below to receive manufacturer's instructions regarding data collection, including histopathological, mechanical and adverse event information.

**Ordering Information**

The Ray TFC\* and Ray TFC Unite\* devices can be ordered from your distributor, or contact:

Surgical Dynamics, Inc. 150 Glover Avenue, Norwalk, CT 06856 USA (800) 822-4734 or (203) 845-1000.

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Manufactured for: Surgical Dynamics Inc., Norwalk, Connecticut 06856

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