



SURGICAL TECHNIQUE

RigidFix

LUMBAR FIXATION SYSTEM

implants for life™

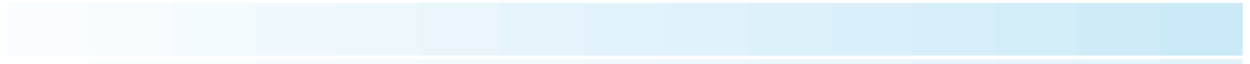
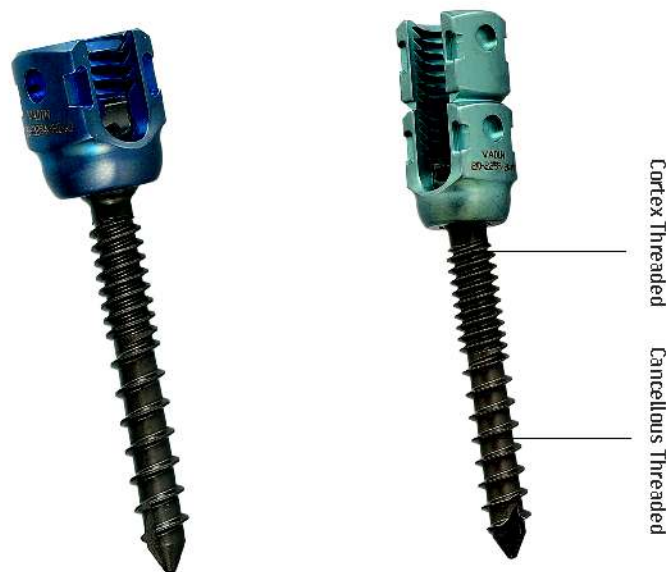


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PRODUCT INFORMATION

All the implants of the RigidFix spine system are manufactured from Titanium alloy. There are available three types of Screws, Multi-Axial, Break-off Multi-Axial and Single Axial, with diameters varying from 4.5 mm to 7.5 mm in 0.5 mm increment and lengths from 25 mm to 55 mm, in 5 mm increment (the lengths refer to the shaft of the screw beneath the head). Multi-Axial Screws can be turned through 360 degrees around their axis and swiveled by 25 degrees in all directions. The double threaded design (cancellous in the distal area and cortical in the proximal) of the Screw shaft significantly increases the pull out strength during in vivo loading. Their heads are designed to accept Rods of both 5.5 mm and 6.0 mm diameter. Moreover, they are color coded by screw diameter as to allow easy and immediate selection of the appropriate Screw during the operation. Particularly, the head of 4.5 mm Screws is grey, of 5.0 mm is magenta, of 5.5 mm is green, of 6.0 mm is yellow, of 6.5 mm is cyan, of 7.0 mm is brown, and of 7.5 mm is dark blue.



Rods are available in multiple lengths from 100 mm to 500 mm (100mm, 120mm, 150 mm, 200 mm, 250 mm, 300 mm, 350 mm, 400 mm, and 500 mm) in 5.5 mm and 6.0 mm diameter. The hex ends allow easy rotation of the rod for the correction of deformities. Rods may be secured in the screw head with the use of either standard Locking Plugs or Bottom Locked Plugs. Plugs are designed with negative angle thread that ensures easy locking and prevents the cross-threading, while it is also reverses the directions of the forces that a set of screws normally exerts on the side walls of implants during final tightening.



The Croos-Links are available in 4 different lengths (50 mm, 60 mm, 70 mm, and 100 mm). Their design allows simple and rapid implantation while they provide increased stability to construction, especially against flexion and rotation forces.



Indications

The implants of RigidFix system are used both for temporary and permanent correction or stabilization of the spine as well as for:

- *Spinal deformities*
- *Spondylolisthesis*
- *Posterior internal fixations for spinal fractures*
- *Degenerative disc disease*
- *Pseudoarthrosis*
- *Tumors in the region of thoracic and lumbar spine*
- *Failed previous fusion*

Contra-indications

The use of the implants of the RigidFix system might be compromised in the following cases:

- *Local and/or systemic infections*
- *Abnormal bone structure of pedicle of vertebral arch*
- *Serious osteoporosis or poor bone quality that may compromise the stability of the implants*
- *Side bending of stiff spine*
- *Allergy to metals*
- *Pregnancy*

SURGICAL TECHNIQUE

Patient Positioning and Incision

The patient should be in an appropriate prone position for a posterior approach. Care should be taken to preserve or in some cases to improve the sagittal alignment of the spine. The patient should be placed on a radiolucent operating table and positioning pads should be placed in all bony prominences as to facilitate the taking of correct lateral and anteroposterior radiographs during the operation. Moreover, it should be ensured that the abdomen is not compressed as to avoid occlusion of the vena cava and/or epidural veins and to preserve free abdominal breathing.

The incision should be straight and strictly along the median line. The length of the incision should be adequate as not to hamper the surgical maneuvers and the correct implantation of the RigidFix implants. Normally, the incision should extend cranially from the spinous process of the next higher vertebra and caudally as far as the spinous process of the next vertebra down.

The type of construct, the most appropriate implants as well as the optimal location for implant insertion should normally be defined during pre-operative planning.

Preparation of the Screw Canal and Decortication of the Pedicle

Initially, the entry points for the creation of the pilot holes are determined with respect to the appropriate anatomical landmarks. Accordingly, the Awl is used to perforate the small cortical crest of the pedicle and to expose the underlying cancellous bone.

Step 1



Next, the entry point is cannulated with either the Straight or the Curved Probe. The Probe should be advanced to the appropriate depth as determined by the surgeon. The depth of Probe's insertion is indicated on the instrument with laser etched grading, measuring from 20 mm to 60 mm with 10 mm increments. These marks are also facilitating the estimation of the proper screw length. The correct insertion of the Probe will allow its' tip to follow the path of least resistance, reducing the potential of perforating the pedicle wall.

Step 2



Inspection of the Drilling Canal and Determination of Screw Length

Step 3



Upon the creation of the screw holes, the Drop Probe should be used to palpate the pilot canal. This particularly flexible instrument carries a ball shaped distal end that enables the examination of the quality of the prepared pedicle canal and mainly assists surgeons to verify that the walls of the pedicle have not been perforated and that cancellous bone is felt through the distal end of the prepared canal.

Tapping of the Screw Canal (Optional Step)

Optional Step

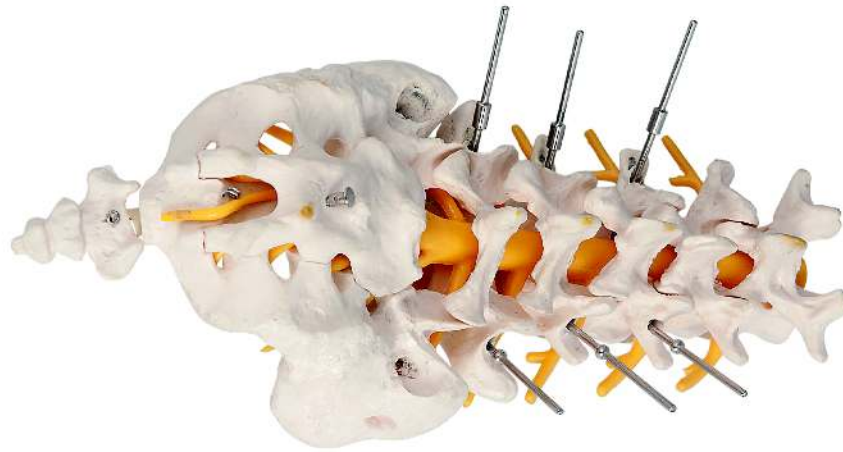


The RigidFix Screws are self-tapping and thus the tapping step is not necessary in most cases. However, if the surgeon considers that tapping should be performed due to the quality of bone (dense, sclerotic, or osteoporotic bone) he has to manage, the RigidFix instrument set contains Taps that are 0.25 mm undersized compared to the corresponding pedicle Screw diameters. The appropriate Tap is inserted through the pedicle into the vertebral body in the same insertion level as the Probe. The Taps are marked with laser etching that indicates the insertion level.

The Drop Probe should be used again to follow the tap threads through the cancellous bone and to palpate for any perforations in the pedicle walls.

Anatomical Verification

Step 4



At this stage, a more meticulous inspection of the prepared bony path should be carried out with the aid of X-rays. Prior to taking radiographs, the X-Ray Markers are inserted into the prepared canals. Care should be taken to position in one side of the spine only the cylindrically shaped markers and on the other side only the spherically-shaped; this helps surgeons to distinguish left and right placement in the patient.

Insertion of the Screws

Step 5



Select the Screws with the proper diameter and length, as they have been estimated by the surgeon during previous steps. For the implantation of screws, the hex end of the Screwdriver should be fully inserted into the head of the screw. Accordingly, the screw driver sleeve is threaded in the head of the screw. The screws are implanted by turning the Screwdriver in clockwise direction.

The Screwdriver may be connected either with a fixed T-Handle or with a fixed Pear-shaped – Handle, or with a Ratcheting Handle.



The fully implanted Screws should extend 50% to 80% into the vertebral body. Once the Screw is inserted, the instrument sleeve is unscrewed by turning it counterclockwise and disengaged from the screw.

The rotation of the head of the screws should be unrestricted even after their implantation. In case that the rotation is limited due to the surrounding bony structures, it is recommended to slightly unclench the screws using again the Screw-driver. The cylindrical thread design of the screws allows a slight unscrewing without compromising the stability of the screw.

Selection and Formation of Rods



Once all screws have been implanted, the appropriate size of rod is selected with the aid of the Rod Template. This flexible instrument is placed on the head of the screws to allow the estimation of the rod length, through the indication of the ruler that it carries on its body, and the necessary amount of bending. If none of the available lengths of Rods deemed suitable for the construct, they may be cut to the appropriate length with the aid of a cutter.

Step 6



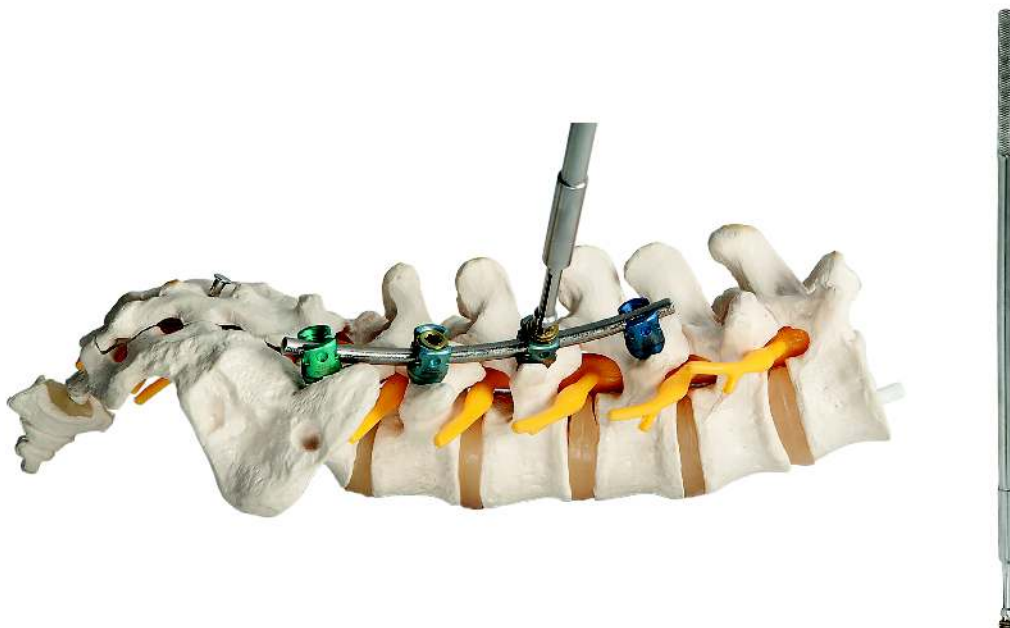
The rods are formed to the appropriate shape with the aid of the Rod Bender. There can be set three different radii (Small, Medium, and Large) by rotating the dial. The contour of the rod may be tested and readjusted by placing it on the heads of the screws. However, only small adjustment should be performed on rods that have already be bend, as the stiffness and the strength of the rods may be downgraded due to material fatigue.

Insertion and Reduction of Rods

Step 7

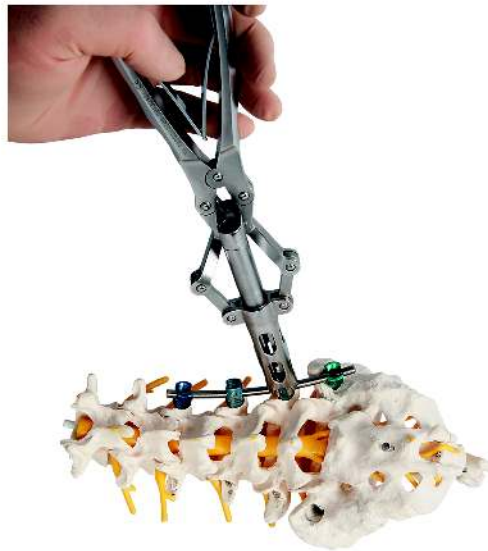


Once the Rod is appropriately contoured, it is laid – down to the pedicle screws with the aid of Rod Holding Forceps.



If the rod is laid down appropriately in the bottom of the head of the screw, the Plugs may be inserted into the implants using the Temporary Tightening Plug Inserter.

Step 8



In cases that the Rod is not fully seated into the bottom of the Head of the Screws, the Rod Reducer is utilized to fully seat the Rod and to simplify the insertion of the Plugs. The Rod Reducer is positioned so that the handles are parallel to the Rod and grasp the Head of the Screw from above. The handles of the instrument are slowly compressed allowing the sleeve to slide down and seat the Rod.



Accordingly, the Temporary Tightening Plug Inserter is inserted through the tube of the Rod Reducer to insert the Plug into the head of the Screw.



If it is required minimal amount of reduction, it also may be performed with the aid of Forceps Rocker or Rocker Clamp. The head of the Screw is grasped from each side with the rocker, ensuring that the rocker cam is positioned above the rod. The rocker is then pushed backward toward the rod, levering the rod into the screw head and accordingly The Temporary Tightening Plug Inserter is used to screw the Plug.

Compression and Distraction

Step 9



Compression or distraction is performed with the aid of Compression or Distraction Clamp, respectively. These maneuvers are performed with the Plug on one side of the motion segment been temporarily tightened, while the Plug on the side of the construction that is to be compressed or distracted been loose. Compression or distraction will occur against the non-tightened implant. The Temporary Tightening Plug Inserter may be used to temporarily lock and secure the Rod and Screw construct.

Care should be taken with all Plugs to ensure that the feet of the Compressor or the Distracter are placed securely against the implant body and not against the Plug. Failure to do this may result in slippage of the implant or premature breaking of the Plug. Once satisfactory compression or distraction has been achieved, final tightening may be performed.

In Situ Bending

Step 10



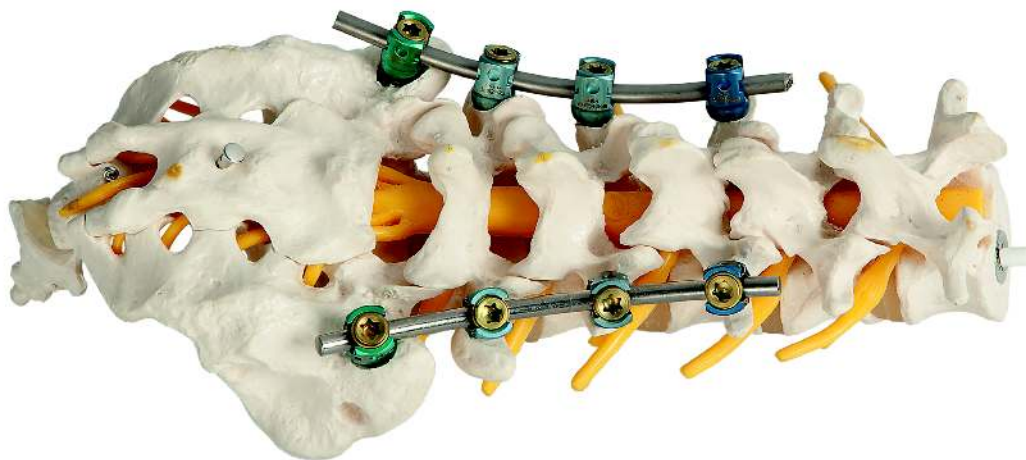
The instrumentation of RigidFix spinal system enables the in situ correction of the Rod contouring. The in situ contouring in the sagittal plane may be achieved using the Reduction Rod Bending Forceps, whereas contouring in the coronal plane may be achieved by employing the L Rod Benders.

Final Locking

Step 11



The final tightening of the Plugs is performed once the Screws and Rods construction has achieved its final configuration. The Torque Limiting Plugdriver is inserted into the cannulated portion of the Reacting Force Wrench, which should be positioned over the Screw and the Rod. The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the Plug is screwed into place securely.

**Note:**

Prior to final fixation of the implants, it should be ensured that there is adequate space between the heads of the Screws in the upper and the lower one-third of the construction for the placement of the Cross-Links

Insertion of Cross-Links

Step 12
















The use of Cross-Links significantly increases the stability of the construction especially against flexion and rotation forces and their implantation is especially indicated in long constructions. Prior to Cross-Link insertion, ensure that the screws of the Cross-Link connectors are loose as to prevent binding during placement onto the Rods of the construct. The appropriate Cross-Link is select and gripped with the Cross-Link Holder. It is placed over Rod at the desired level and the Connectors are adjusted until they can be positioned into both rods. Accordingly, the Plug Inserter is used to tighten the Cross-Link construction into place.


ORDERING INFORMATION

Instruments

	
L Rod Bender (Left) T2252-3600L	
L Rod Bender (Right) T2252-3600R	
Hex Screwdriver T2252 -1000	
Temporary Tightening Plug Inserter - T2252-0800	
Stop Limited Drill Boring Driver - T2252-3500	
Double-head Rod Rotation Wrench - T2252-2000	
Star Screwdriver 5.6 T2252-0900	
Torque Limiting Plugdriver T2252-3300	
Reduction Rod Bending Forceps (Left) - T2252-1900L	
Reduction Rod Bending Forceps (Right) - T2252-1900R	
Rod Bender T2252-2500	



<p>Reacting Force Wrench T2252-1300</p>	
<p>Reduction Reacting Force Wrench T2252-1300</p>	
<p>Quick Coupling T-handle T2252-1200</p>	
<p>Pear-shaped – Handle T2252-1100</p>	
<p>Ratcheting Handle T2252-3400</p>	
<p>ScrewT ap ø6 .5 T2252-0101</p>	
<p>Screw Tap ø 5.5 T2252-0100</p>	
<p>ScrewT ap ø4 .5 T2252-0102</p>	
<p>Rod Template T2252-2100</p>	
<p>Awl T2252-0200</p>	
<p>Straight Probe T2252-0300</p>	
<p>Curved Probe T2252-0400</p>	
<p>Reduction Screw Tab Breaker</p>	

T2252-2300	
Drop Probe T2252-0500	
Screw Driver T2252-1800	
	
Rod Reductor Sleeve T2252-2800	
Compression Clamp T2252-3200	
Rod Reducer T2252-2700	
Distraction Clamp T2252-3100	
Cross-Link Holder T2252-2900	
Rocking Forceps T2252-2600	
Rocker Clamp T2252-2200	
Rod Rocking Forceps VA T2252-3000	
Rod Rotation Holder Clamp T2252-2400	

Implants



Ref No	5.5 mm Diameter Rod
20-2231-2510	5.5 mm Diameter Rod, 100 mm Long
20-2231-2512	5.5 mm Diameter Rod, 120 mm Long
20-2231-2515	5.5 mm Diameter Rod, 150 mm Long
20-2231-2520	5.5 mm Diameter Rod, 200 mm Long
20-2231-2525	5.5 mm Diameter Rod, 250 mm Long
20-2231-2530	5.5 mm Diameter Rod, 300 mm Long
20-2231-2535	5.5 mm Diameter Rod, 350 mm Long
20-2231-2540	5.5 mm Diameter Rod, 400 mm Long
20-2231-2550	5.5 mm Diameter Rod, 500 mm Long
Ref No	6.0 mm Diameter Rod
20-2211-2610	6.0 mm Diameter Rod, 100 mm Long
20-2211-2612	6.0 mm Diameter Rod, 120 mm Long
20-2211-2615	6.0 mm Diameter Rod, 150 mm Long
20-2211-2620	6.0 mm Diameter Rod, 200 mm Long
20-2211-2625	6.0 mm Diameter Rod, 250 mm Long
20-2211-2630	6.0 mm Diameter Rod, 300 mm Long
20-2211-2635	6.0 mm Diameter Rod, 350 mm Long
20-2211-2640	6.0 mm Diameter Rod, 400 mm Long
20-2211-2650	6.0 mm Diameter Rod, 500 mm Long



Ref No	5.5 mm Diameter CrossLinks
20-2247-2305	5.5 mm Diameter Crosslinks, 50 mm Long
20-2247-2306	5.5 mm Diameter Crosslinks, 60 mm Long
20-2247-2307	5.5 mm Diameter Crosslinks, 70 mm Long
20-2247-2310	5.5 mm Diameter Crosslinks, 100 mm Long
Ref No	6.0 mm Diameter CrossLinks
20-2248-2350	6.0 mm Diameter Crosslinks, 50 mm Long
20-2248-2360	6.0 mm Diameter Crosslinks, 60 mm Long
20-2248-2370	6.0 mm Diameter Crosslinks, 70 mm Long
20-2248-2380	6.0 mm Diameter Crosslinks, 80 mm Long
20-2248-2390	6.0 mm Diameter Crosslinks, 90 mm Long
20-2248-2310	6.0 mm Diameter Crosslinks, 100 mm Long



Ref No	Locking Plugs
20-2252-2001	Locking Plug (Standard)
20-2252-2002	Locking Plug (Bottom Locked)

Single Axial Screws (Double Core and Double Threaded Type)



Ref No	Description
20-2272-2G25	4.5 mm Diameter, 25 mm Long
20-2272-2G30	4.5 mm Diameter, 30 mm Long
20-2272-2G35	4.5 mm Diameter, 35 mm Long
20-2272-2G40	4.5 mm Diameter, 40 mm Long
20-2272-2G45	4.5 mm Diameter, 45 mm Long
20-2272-2H25	5.0 mm Diameter, 25 mm Long
20-2272-2H30	5.0 mm Diameter, 30 mm Long
20-2272-2H35	5.0 mm Diameter, 35 mm Long
20-2272-2H40	5.0 mm Diameter, 40 mm Long
20-2272-2H45	5.0 mm Diameter, 45 mm Long
20-2272-2I25	5.5 mm Diameter, 25 mm Long
20-2272-2I30	5.5 mm Diameter, 30 mm Long
20-2272-2I35	5.5 mm Diameter, 35 mm Long
20-2272-2I40	5.5 mm Diameter, 40 mm Long
20-2272-2I45	5.5 mm Diameter, 45 mm Long
20-2272-2J25	6.0 mm Diameter, 25 mm Long
20-2272-2J30	6.0 mm Diameter, 30 mm Long
20-2272-2J35	6.0 mm Diameter, 35 mm Long
20-2272-2J40	6.0 mm Diameter, 40 mm Long
20-2272-2J45	6.0 mm Diameter, 45 mm Long
20-2272-2J50	6.0 mm Diameter, 50 mm Long
20-2272-2J55	6.0 mm Diameter, 55 mm Long
20-2272-2K25	6.5 mm Diameter, 25 mm Long
20-2272-2K30	6.5 mm Diameter, 30 mm Long
20-2272-2K35	6.5 mm Diameter, 35 mm Long
20-2272-2K40	6.5 mm Diameter, 40 mm Long
20-2272-2K45	6.5 mm Diameter, 45 mm Long
20-2272-2K50	6.5 mm Diameter, 50 mm Long
20-2272-2K55	6.5 mm Diameter, 55 mm Long
20-2272-2L25	7.0 mm Diameter, 25 mm Long
20-2272-2L30	7.0 mm Diameter, 30 mm Long
20-2272-2L35	7.0 mm Diameter, 35 mm Long
20-2272-2L40	7.0 mm Diameter, 40 mm Long
20-2272-2L45	7.0 mm Diameter, 45 mm Long
20-2272-2L50	7.0 mm Diameter, 50 mm Long
20-2272-2L55	7.0 mm Diameter, 55 mm Long
20-2272-2M25	7.5 mm Diameter, 25 mm Long
20-2272-2M30	7.5 mm Diameter, 30 mm Long
20-2272-2M35	7.5 mm Diameter, 35 mm Long
20-2272-2M40	7.5 mm Diameter, 40 mm Long
20-2272-2M45	7.5 mm Diameter, 45 mm Long
20-2272-2M50	7.5 mm Diameter, 50 mm Long
20-2272-2M55	7.5 mm Diameter, 55 mm Long

Multi-Axial Screws

(Double Core and Double Threaded Type)



Ref No	Description
20-2254-2G25	4.5 mm Diameter, 25 mm Long
20-2254-2G30	4.5 mm Diameter, 30 mm Long
20-2254-2G35	4.5 mm Diameter, 35 mm Long
20-2254-2G40	4.5 mm Diameter, 40 mm Long
20-2254-2G45	4.5 mm Diameter, 45 mm Long
20-2254-2H25	5.0 mm Diameter, 25 mm Long
20-2254-2H30	5.0 mm Diameter, 30 mm Long
20-2254-2H35	5.0 mm Diameter, 35 mm Long
20-2254-2H40	5.0 mm Diameter, 40 mm Long
20-2254-2H45	5.0 mm Diameter, 45 mm Long
20-2254-2I25	5.5 mm Diameter, 25 mm Long
20-2254-2I30	5.5 mm Diameter, 30 mm Long
20-2254-2I35	5.5 mm Diameter, 35 mm Long
20-2254-2I40	5.5 mm Diameter, 40 mm Long
20-2254-2I45	5.5 mm Diameter, 45 mm Long
20-2254-2J25	6.0 mm Diameter, 25 mm Long
20-2254-2J30	6.0 mm Diameter, 30 mm Long
20-2254-2J35	6.0 mm Diameter, 35 mm Long
20-2254-2J40	6.0 mm Diameter, 40 mm Long
20-2254-2J45	6.0 mm Diameter, 45 mm Long
20-2254-2J50	6.0 mm Diameter, 50 mm Long
20-2254-2J55	6.0 mm Diameter, 55 mm Long
20-2254-2K25	6.5 mm Diameter, 25 mm Long
20-2254-2K30	6.5 mm Diameter, 30 mm Long
20-2254-2K35	6.5 mm Diameter, 35 mm Long
20-2254-2K40	6.5 mm Diameter, 40 mm Long
20-2254-2K45	6.5 mm Diameter, 45 mm Long
20-2254-2K50	6.5 mm Diameter, 50 mm Long
20-2254-2K55	6.5 mm Diameter, 55 mm Long
20-2254-2L25	7.0 mm Diameter, 25 mm Long
20-2254-2L30	7.0 mm Diameter, 30 mm Long
20-2254-2L35	7.0 mm Diameter, 35 mm Long
20-2254-2L40	7.0 mm Diameter, 40 mm Long
20-2254-2L45	7.0 mm Diameter, 45 mm Long
20-2254-2L50	7.0 mm Diameter, 50 mm Long
20-2254-2L55	7.0 mm Diameter, 55 mm Long
20-2254-2M25	7.5 mm Diameter, 25 mm Long
20-2254-2M30	7.5 mm Diameter, 30 mm Long
20-2254-2M35	7.5 mm Diameter, 35 mm Long
20-2254-2M40	7.5 mm Diameter, 40 mm Long
20-2254-2M45	7.5 mm Diameter, 45 mm Long
20-2254-2M50	7.5 mm Diameter, 50 mm Long
20-2254-2M55	7.5 mm Diameter, 55 mm Long

Break-off Multi-Axial Screws

(Double Core and Double Threaded Type)



Ref No	Description
20-2255-2G25	4.5 mm Diameter, 25 mm Long
20-2255-2G30	4.5 mm Diameter, 30 mm Long
20-2255-2G35	4.5 mm Diameter, 35 mm Long
20-2255-2G40	4.5 mm Diameter, 40 mm Long
20-2255-2G45	4.5 mm Diameter, 45 mm Long
20-2255-2H25	5.0 mm Diameter, 25 mm Long
20-2255-2H30	5.0 mm Diameter, 30 mm Long
20-2255-2H35	5.0 mm Diameter, 35 mm Long
20-2255-2H40	5.0 mm Diameter, 40 mm Long
20-2255-2H45	5.0 mm Diameter, 45 mm Long
20-2255-2I25	5.5 mm Diameter, 25 mm Long
20-2255-2I30	5.5 mm Diameter, 30 mm Long
20-2255-2I35	5.5 mm Diameter, 35 mm Long
20-2255-2I40	5.5 mm Diameter, 40 mm Long
20-2255-2I45	5.5 mm Diameter, 45 mm Long
20-2255-2J25	6.0 mm Diameter, 25 mm Long
20-2255-2J30	6.0 mm Diameter, 30 mm Long
20-2255-2J35	6.0 mm Diameter, 35 mm Long
20-2255-2J40	6.0 mm Diameter, 40 mm Long
20-2255-2J45	6.0 mm Diameter, 45 mm Long
20-2255-2J50	6.0 mm Diameter, 50 mm Long
20-2255-2J55	6.0 mm Diameter, 55 mm Long
20-2255-2K25	6.5 mm Diameter, 25 mm Long
20-2255-2K30	6.5 mm Diameter, 30 mm Long
20-2255-2K35	6.5 mm Diameter, 35 mm Long
20-2255-2K40	6.5 mm Diameter, 40 mm Long
20-2255-2K45	6.5 mm Diameter, 45 mm Long
20-2255-2K50	6.5 mm Diameter, 50 mm Long
20-2255-2K55	6.5 mm Diameter, 55 mm Long
20-2255-2L25	7.0 mm Diameter, 25 mm Long
20-2255-2L30	7.0 mm Diameter, 30 mm Long
20-2255-2L35	7.0 mm Diameter, 35 mm Long
20-2255-2L40	7.0 mm Diameter, 40 mm Long
20-2255-2L45	7.0 mm Diameter, 45 mm Long
20-2255-2L50	7.0 mm Diameter, 50 mm Long
20-2255-2L55	7.0 mm Diameter, 55 mm Long
20-2255-2M25	7.5 mm Diameter, 25 mm Long
20-2255-2M30	7.5 mm Diameter, 30 mm Long
20-2255-2M35	7.5 mm Diameter, 35 mm Long
20-2255-2M40	7.5 mm Diameter, 40 mm Long
20-2255-2M45	7.5 mm Diameter, 45 mm Long
20-2255-2M50	7.5 mm Diameter, 50 mm Long
20-2255-2M55	7.5 mm Diameter, 55 mm Long



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