

B-Dyn™

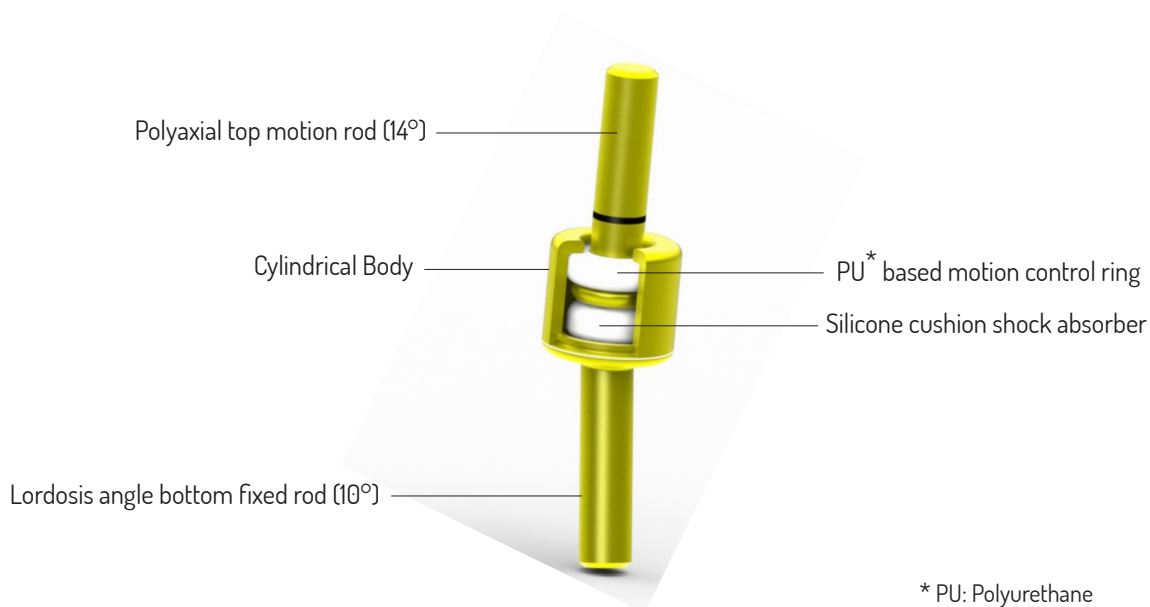
Posterior Dynamic Stabilization System



Surgical Technique

PRESENTATION / INTRODUCTION

The sterile spinal dynamic posterior stabilization device B-DynTM is intended to restore or to preserve, as long as possible, the normal stabilization of the segment of the spine from the thoracic vertebra T10 to the sacrum S1 by maintaining the anatomical lordosis and supporting the shock absorption of the intervertebral discs.



The sterile spinal dynamic posterior stabilization device B-Dyn™ is composed of the following components:

> B-DYN

Spinal shock absorber

Size of B-Dyn	Small	Medium	Small	Medium
Diameter of rod	5.0 mm	5.0 mm	5.5 mm	5.5 mm
Reference	RCBDYSD50U	RCBDYMD50U	RCBDYSD55U	RCBDYMD55U



B-Dyn Ø 5.0



B-Dyn Ø 5.5

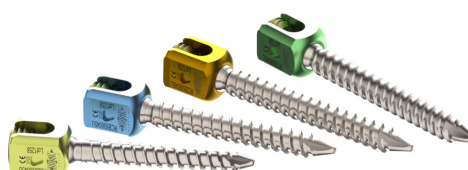
*Small B-Dyn references can be used with 4 pedicle screws
Medium B-Dyn references can be used with 6 pedicle screws.*

> POLYAXIAL PEDICLE SREWS

Length 30 to 55 mm

Diameter	5.5 mm	6.0 mm	6.5 mm	7.0 mm
Diameter of rod	5.0 mm			
Reference	RCB505530U	RCB506030U	RCB506530U	RCB507030U
	RCB505535U	RCB506035U	RCB506535U	RCB507035U
	RCB505540U	RCB506040U	RCB506540U	RCB507040U
	RCB505545U	RCB506045U	RCB506545U	RCB507045U
	RCB505550U	RCB506050U	RCB506550U	RCB507050U
	RCB505555U	RCB506055U	RCB506555U	RCB507055U

The references SD55 and MD55 of B-Dyn shall be fixed to vertebrae with a fixation system adapted to this device and validated by Cousin Biotech.



SURGICAL TECHNIQUE KIT CONTENT



Trial prosthesis SD50
RCBANTD50U



Torx 25 screwdriver
RCBANTX25U



Rod fork
RCBANROF0U



Thoracic perforator
RCBANTPERU



Tap Ø 5.0 mm
RCBANTA50U



Distraction forceps
RCBANDISTU



Lumbar perforator
RCBANLPERU



Counter torque
RCBANCOT0U



Compression forceps
RCBANCOMPU



Square awl
RCBANSQAWU



Polyaxial Screwdriver
RCBANPSDRU



Long Rod Bender
RCBANLRBEU



Rod pusher
RCBANRODPU



Sounder
RCBANSOUNU



Dynamometric handle 10 NM
RCBANDH10U



Large Set Screw Holder
RCBANLSSHU



BDyn Holder
RCBANBDH0U



Ratched Straight Handle
RCBANRUSHU



Small Set Screw Holder
RCBANSSSHU



Rod holder
RCBANRH50U

INDICATIONS

The sterile spinal dynamic posterior stabilization device B-Dyn™ is intended for posterior stabilization from thoracic vertebrae T10 to sacrum, with or without bone graft for the following indications:

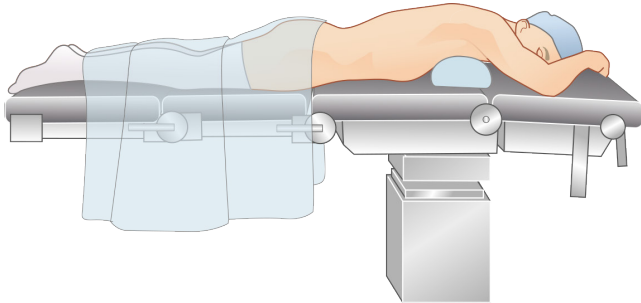
- *Degenerative intervertebral disc disease and/or articular facets confirmed by further examinations*
- *Spinal canal stenosis*
- *Degenerative spondylolisthesis grade 1*
- *Segmental instability*

Contra-indications: refer to B-Dyn™'s Instructions For Use (NOT254)

CONTRA-INDICATIONS

- *Active infectious process or significant risk of infection (immunocompromise)*
- *Signs of local inflammation*
- *Fever or leukocytosis*
- *Morbid obesity*
- *Pregnancy*
- *Mental illness*
- *Grossly distorted anatomy caused by genital abnormalities*
- *Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of the sedimentation rate unexplained by other diseases, elevation of the white blood count*
- *Suspected or documented metal allergy or intolerance*
- *Any case where the implant components selected for use would be too large or too small to achieve a successful result*
- *Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality*
- *Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance*
- *Any patient unwilling to follow postoperative instructions*
- *Any case not describe in the indications*
- *Traumas (i.e. fracture or dislocation)*
- *Abnormal curvatures (i.e. scoliosis and/or hyper lordosis)*
- *Tumors.*
- *Spondylolisthesis grade 2 and more*
- *Pseudarthrosis and/or failed previous fusion*
- *Severe bone resorption, osteomalacia, severe osteoporosis*

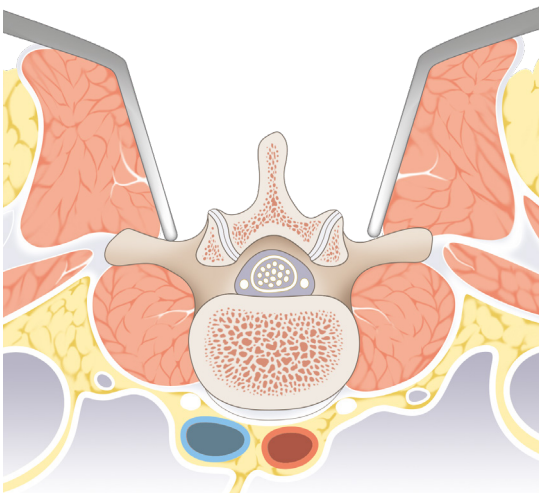
1 POSITIONING



Prone position under global or regional anesthesia.

The affected level is monitored by X-Ray.

2 INCISION



Incision on the midline on the outer edge of the spinous processes. The muscles are laterally retracted from spinous processes.

3 PREPARATION

Prepare the entry point at the cortical bone with the help of a square awl (RCBANSQAWU).

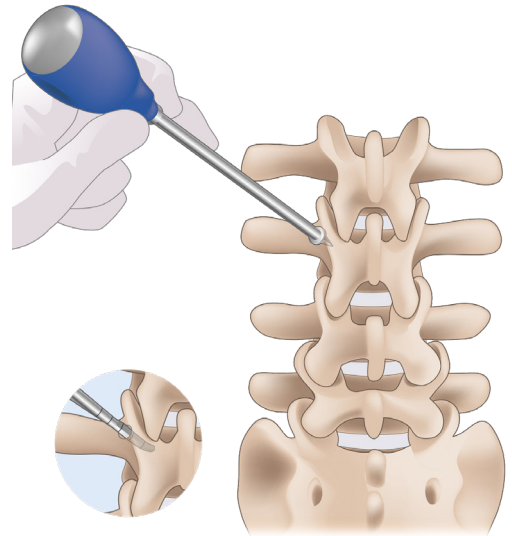
Use the perforators to create the channel for the screw.

Two graduated perforators are available:

- thoracic perforator (RCBANTPERU)
- lumbar perforator (RCBANLPERU)

The perforators are graduated and allow the surgeon to estimate the length of screw.

With the sounder (RCBANSOUNU), the surgeon will ensure the good pedicular preparation. To improve the optimal passage of the pedical screw, it's possible to use the tap Ø 5.0mm. (RCBANTA50U)



4 INSERTION OF PEDICLE SCREWS

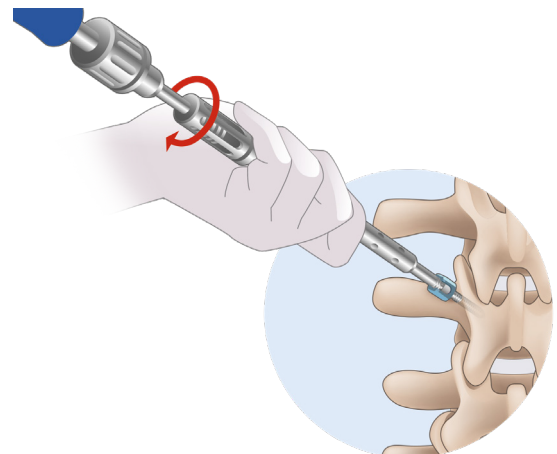
The diameter and the length of the screw are determined by the surgeon.

Assemble the Rached Universal Straight Handle (RCBANRUSHU) on the Polyaxial Screwdriver (RCBANPSDRU).

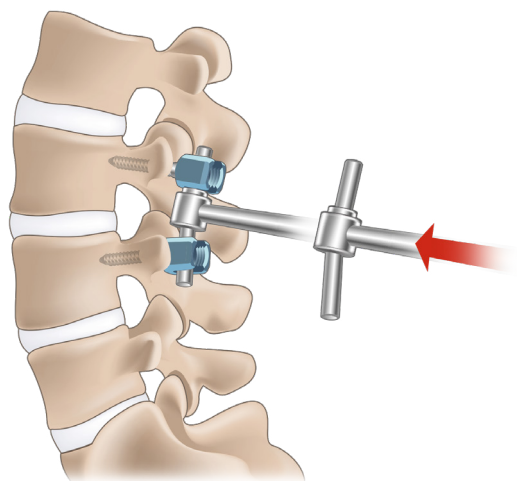
Insert the pedical screw into the bore of the screwdriver.

Once the screw is in place, remove the screwdriver from the screw by taking off from the wheel.

The screws are placed lateraly to the facet joint.



5 USE OF TRIAL PROSTHESIS

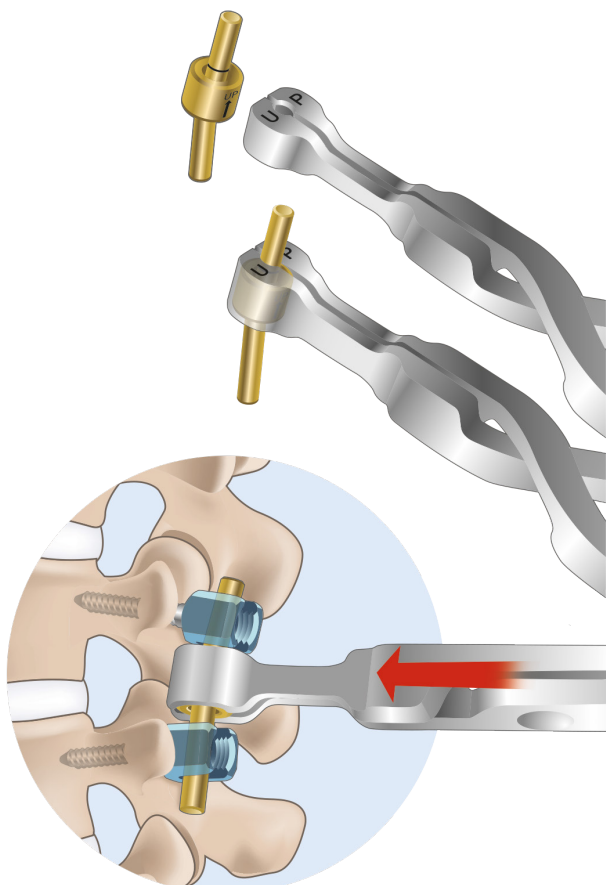


It is necessary to optimize the location of polyaxial screw in order to facilitate the positioning of B-Dyn™ device.

The Trial Prosthesis TD50 BDyn™ (RCBANTD50U) enables to better estimate the bulk of the B-Dyn™ dynamic rod and optimise the implantation of screw. It must be perfectly flattened against the bottom of polyaxial screws heads without affecting articular facets.

💡 If there is not enough room for the spacer, it is possible to remove part of the bone from facet joint, preserving the capsule.


💡 It's possible to re-adjust the height of the screw by using screwdriver.



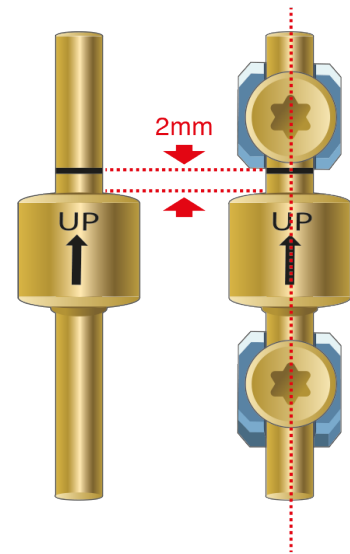
6 B-Dyn™ DYNAMIC ROD POSITIONING

The upper jaws of the rod holder (RCBANBDHOU) must be positioned exactly on the black mark of the polyaxial rod.

Positioning the B-Dyn™ dynamic rod into the heads of polyaxial screws with the help of the rod Holder (RCBANBDHOU) and precisely adjust the position of the polyaxial top motion rod of B-Dyn™ dynamic rod.

 It should strictly keep a reserve of 2mm between the cylindrical body and the central screw head, in order to have an optimal dynamic behavior. The arrow must be aligned with the two screw head opening.

Perform a pre-tightening of polyaxial screw plug with the Small Set Screw Holder (**RCBANSSSHU**) or Large Set Screw Holder (**RCBANLSSHU**).

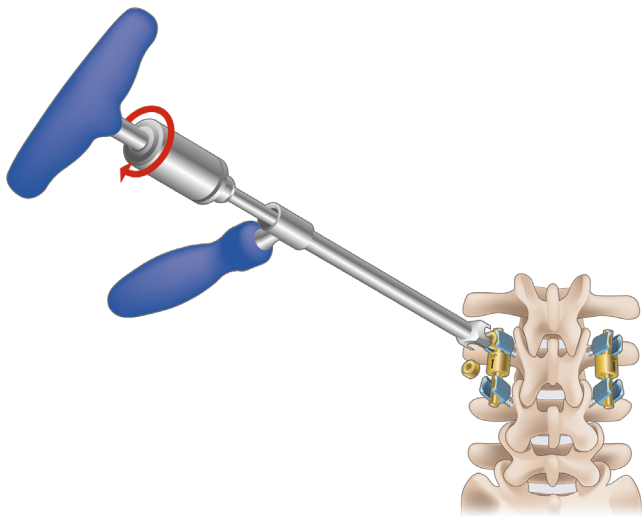


7 FINAL LOCKING OF TIGHTENING PLUGS

Assemble the Dynamometric Handle (**RCBANDH10U**) on the Torx 25 Screwdriver (**RCBANTX25U**) and insert into the Counter Torque (**RCBANCOTOU**). This enables the tighten of the set screw to a torque of 10Nm.

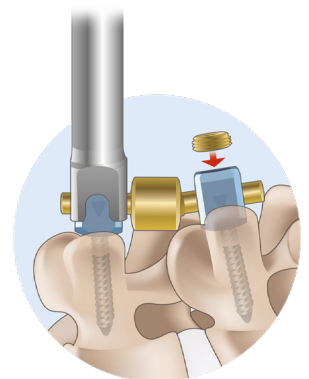
Counter Torque may be used to correct better alignment of screw heads.

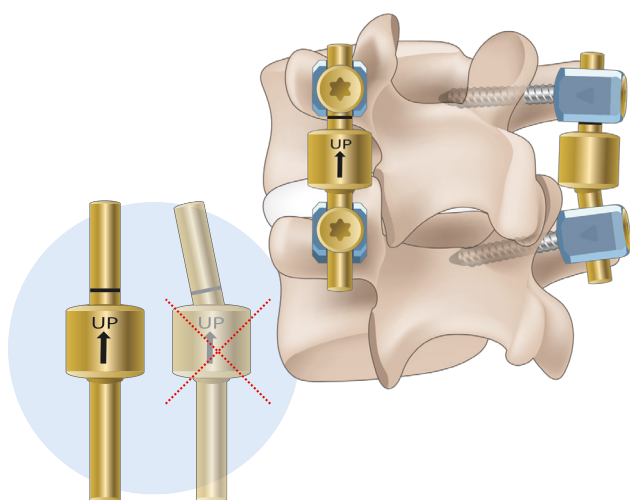
Usage of CounterTorque enables to make final tightening easier and make sure the rule of 2mm guarantee good functioning of B-Dyn™ device.



 The Counter Torque has 4 sides:

- 3 of these sides have 2mm thickness. They must be used for tightening the set screw, above the cylindrical body
- 1 side has 0.3 mm thickness. This will serve only for tightening the set screw below the cylindrical body.





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ASSEMBLING INSPECTION

Check the assembling with radiographies.

The B-Dyn™ must always maintain its original profiles.

The polyaxial B-Dyn™ top motion rod must maintain:

- its alignment in the frontal and sagittal plane with the cylindrical bodies
- the depreciation reserve of 2mm for an optimum in-situ function of the device.



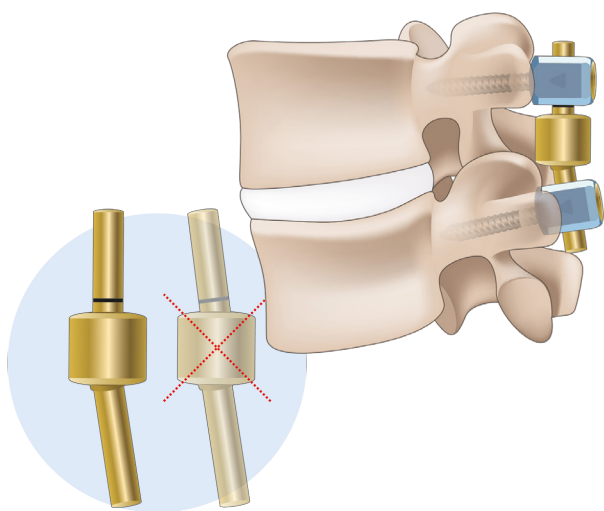
Keep the original alignment of the implant



Keep the shock absorption reserve of 2 mm



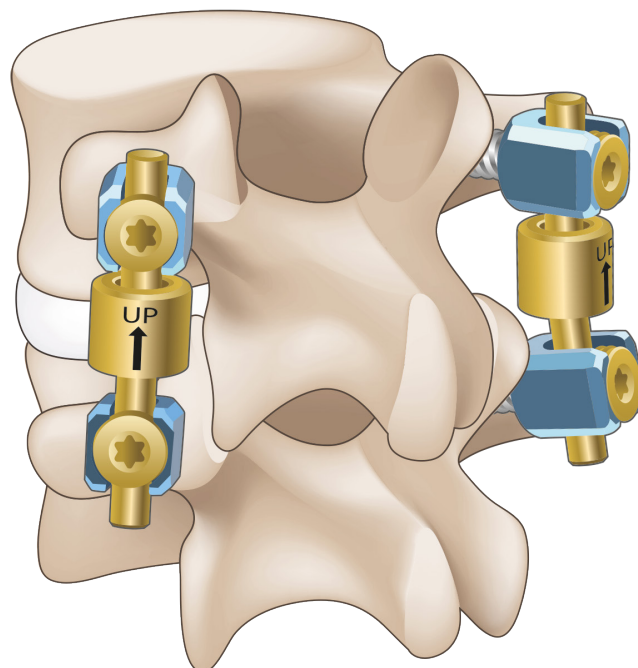
In case of mis-alignment of the mobile rod, the surgeon can realign it by using the Counter Torque to turn the head of the screw in the access of the cylindrical body.



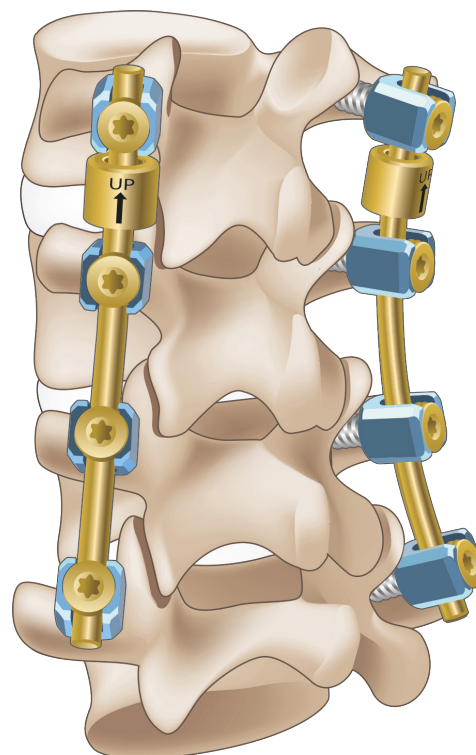
9 FINAL ASSEMBLING

Steps 3 to 8 are repeated for the implantation of a second B-Dyn™ device.

*Final assembling of the
B-Dyn Ø 5.0 - Small
Ref: RCBDYSD50U*

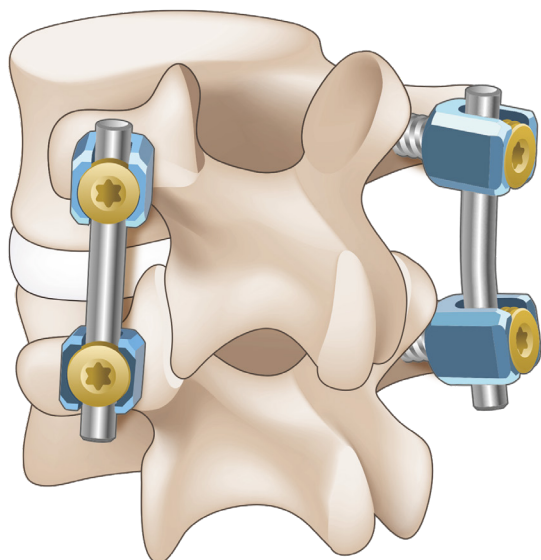


*Final assembling of the
B-Dyn Ø 5.0 - Medium
Ref: RCBDYMD50U*



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FUSION SURGERY WITH B-DYN RIGID ROD



In case of revision surgery, B-Dyn[™] dynamic rod may be replaced by B-Dyn[™] rigid rod.

There are two lengths of rod:

- Rod 47 mm (RCBFUL047U) to replace the BDyn[™] Ø5.0 - Small (RCBDYSD50U)
- Rod 107 mm (RCBFUL107U) to replace the BDyn[™] Ø5.0 Medium (RCBDYMD50U)



Rigid rod for replacement 47 mm
(RCBFUL047U)



Rigid rod for replacement 107 mm
(RCBFUL107U)



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