

Fitbone™

Intramedullary Lengthening System

Retraction Control Set Quick Guide



Retraction Control Set

The Retraction Control Set is dedicated to cases where retraction is medically necessary, e.g. unintended over-distraction. This Quick Guide describes the special features of the Retraction Control Set.

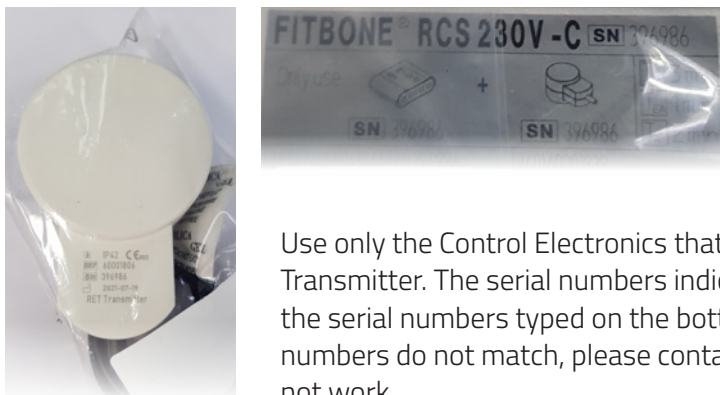
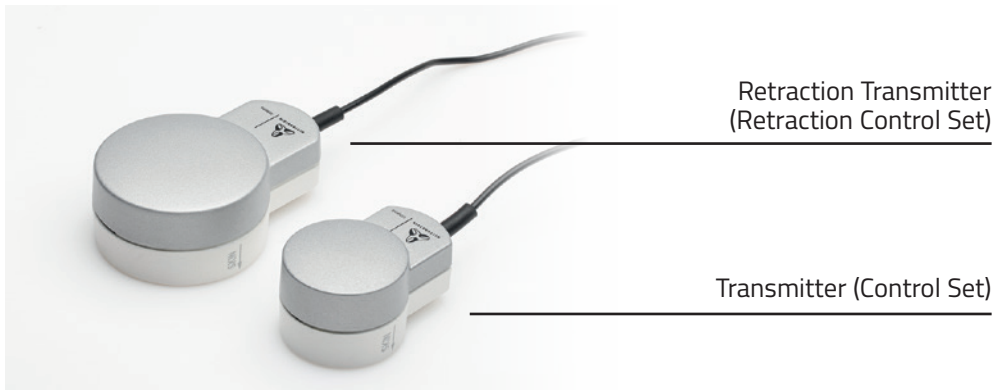
Precaution: Retraction must not be carried out over the initial total length of the intramedullary lengthening nail since this might cause jamming of the implant. During energy transmission, monitor the retraction with continuous X-ray monitoring.

Note: Retraction is only allowed to be performed by the surgeon.

Retraction Control Set Components



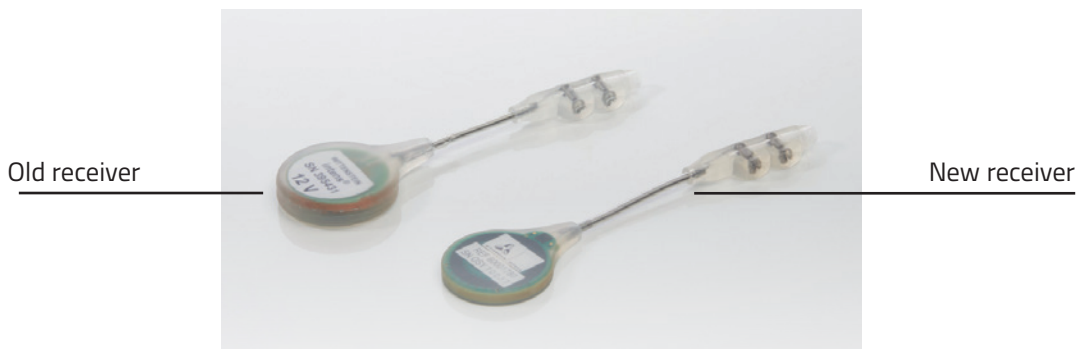
The Retraction Control Set Components consist of the Control Electronics and a retraction transmitter. The Retraction Control Set Transmitter is larger and heavier than the transmitter of the control set.



Use only the Control Electronics that were supplied with the Retraction Transmitter. The serial numbers indicated on each device must correspond to the serial numbers typed on the bottom of the Control Electronics. If the serial numbers do not match, please contact Orthofix as the Retraction Control Set will not work.

Note: please notice that at the back of the Control Electronics there is a label indicating the above mentioned point.

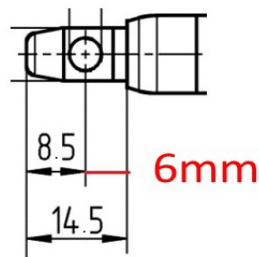
The Retraction Control Set will only retract FITBONE® Nails that are connected to the new Receiver (please see below).

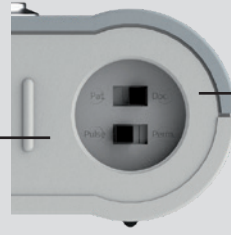
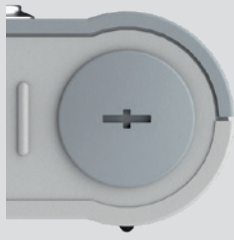


Please note that 27 impulses are only equivalent to 1mm, assuming no soft tissue resistance and full energy transmission. If the Receiver is situated deeper than 10mm under the skin or the Transmitter is not positioned exactly concentric to the Receiver, the energy transmission is reduced. For an exact measurement of the distraction or retraction please refer to the patient's x-ray images.

The starting position (pre-distraction) of the telescopic portion of all TAA Nails measures 6mm (red line on diagram) to the tip of the nail (please see below).

In order to accurately determine length of distraction, please use these points as reference.





Switch Patient/Doctor Mode
Enables Doctor or Patient button.
In the "Doc" position the transmission time is not limited.
In the "Pat" position the transmission time is limited to 90 seconds.



Switch Pulsating/Permanent Mode

Enables pulsating or permanent energy transmission. Please note that permanent energy transmission is only possible in Doctor mode. The pulsating mode transfers energy for 1 second with 9 second breaks in between. During the energy transfer the yellow light blinks 5 times. Lengthening velocity pulsating mode: 1mm/4.5 min
Lengthening velocity permanent mode: 1mm/30 sec

Retraction Control Set speed and retraction force

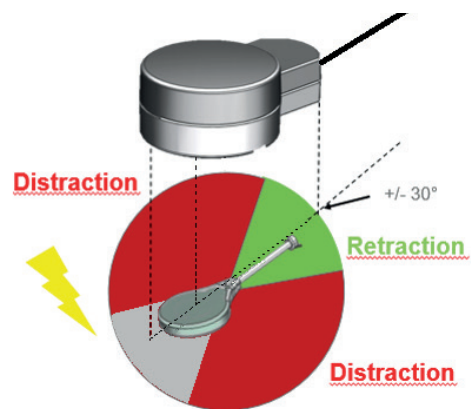
During retraction the force is equal to approximately half of the distraction force. Please note that overloading the nail during retraction may result in damage to the nail.

Positioning of the transmitter

The transmitter and the receiver should be placed concentrically to achieve optimal energy transfer (as shown in the picture below).

Place the transmitter over the receiver so that they match symmetrically. The portion of the transmitter with the cable exiting should be in the same orientation and directly above the section of the receiver where the cable exits as shown. To ensure retraction, the orientation must be within $\pm 30^\circ$ of this position (green zone), otherwise distraction may occur (red zone).

Note: If the transmitter is angulated more than $\pm 30^\circ$ (red zone), nail distraction will take place. Failure to place the transmitter and the receiver concentrically will result in a reduced energy transfer and a decrease in retraction speed.



Instructions for retraction



Locate the Receiver via x-rays or ultrasound and mark the position of the Receiver and, most importantly, the position of the cable attached to the Receiver.



Open the Retraction Control Set Box



Take out the Control Electronics

Note: please notice that on the front and back of the Control Electronics the labels (underneath and left) indicate that this Control Electronics is for retraction.

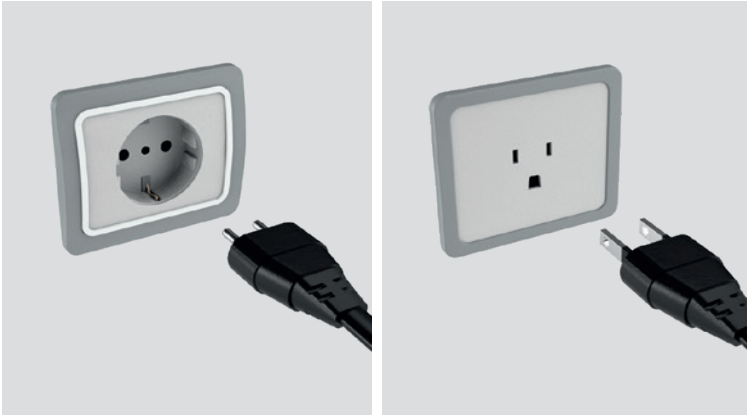


Take out the power cable





▶ Take out the Retraction Transmitter



▶ Plug in the power cable



▶ Plug the Retraction Transmitter into the Control Electronics



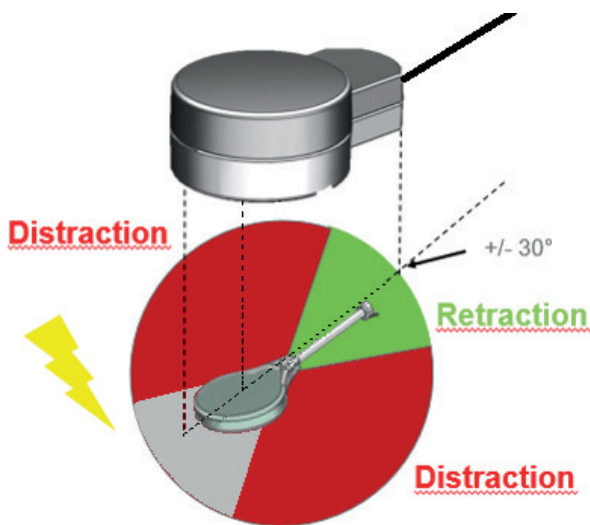
▶ Turn on the Control Electronics



▶ Place the Stethoscope earbuds in the ears.

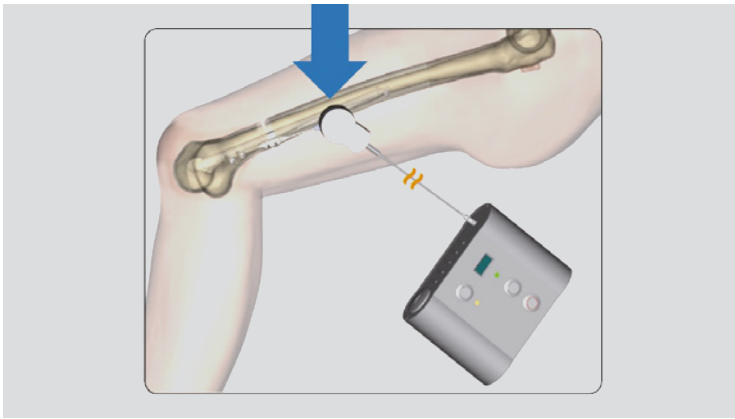


▶ Find the marking "SKIN" on the Retraction Transmitter indicating the side to be in contact with skin.



Place the Retraction Transmitter over the receiver so that they match symmetrically. The portion of the Retraction Transmitter with the cable exiting should be in the same orientation and directly above the section of the receiver where the cable exits as shown. To ensure retraction, the orientation must be within $\pm 30^\circ$ of this position (green zone), otherwise distraction may occur (red zone).

Note: If the Retraction Transmitter is angulated more than $\pm 30^\circ$ (red zone), nail distraction will take place.



Please note that there is a change in acoustic pitch according to orientation of the Retraction Transmitter (please refer to above picture): during distraction the pitch is low, during retraction the pitch is higher.

To confirm retraction, please place the Stethoscope close to the Receiver. The Receiver is the source of the higher pitched sound and not the motor.



On the front of the FITBONE Control Electronics, press the switch labeled "Doctor". The switch lights up blue after being pressed.



Use of continuous operation mode must be interrupted after a maximum of 20 seconds for a minimum of 2 minutes to prevent excessive heat in the tissue between the Retraction Transmitter and Receiver. In Doctor Mode (continuous operation), the Transmitter can reach a maximum temperature of 47.2°C / 116.96 °F.



If placement is correct, the yellow "Transmit" LED will flash 5 times within one second. You'll also see the counting on the display.



By pressing the reset button, the counter will return to 0 (zero). 27 impulses are equivalent to 1mm.



▶ Turn off the Control Electronics and disconnect the cables.

For a full list of warnings and further information, please refer to the Instructions for use FITBONE Control Set and FITBONE Clinician Guide.

Distributed by:



Manufacturer info is available on the product labels and relevant IFUs.