MULTIGEN+
THE TOTAL KNEE SYSTEM

KNEE BALANCER

SURGICAL TECHNIQUE
& INSTRUMENT MANUAL

Lima Corporate
Orthopaedic motion

KNEE BALANCER SURGICAL TECHNIQUE

Index

Limacorporate spa, as manufacturer of prosthesis device, does not practice medicine. This surgical technique brochure has been developed in consultation with an experienced surgeons team and provides the surgeon with general guidance when implanting MULTIGEN PLUS using KNEE BALANCER. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each individual patient. For further information about our products, please visit our web site at www.limacorporate.com

◆ = *In the images of this publication the horizontal lines, the letters and the numbers indicating the forces and the gap are highlighted in red for purely illustrative purposes.*

LEONARDO DA VINCI: the Vitruvian Man. Studies of human proportions (1490)

Introduction

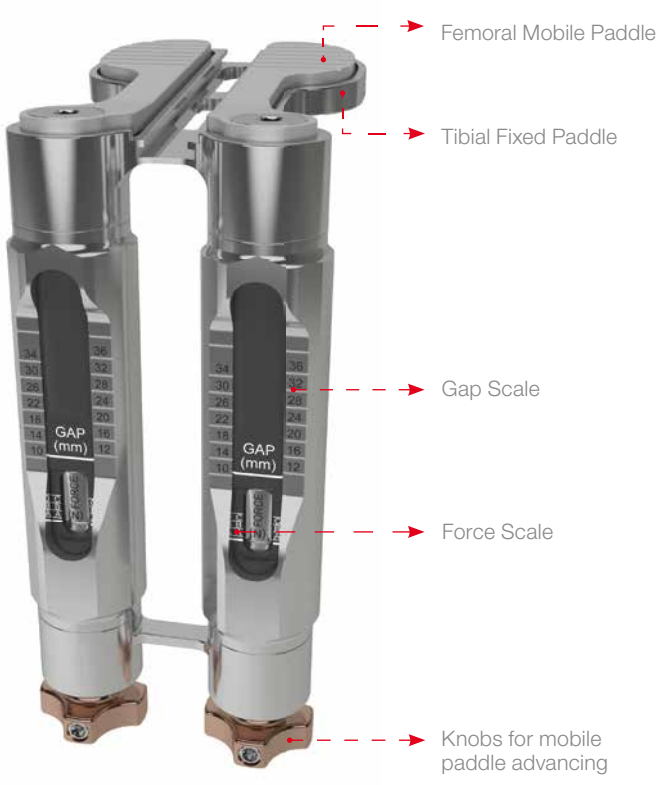


Figure 1

Figure 2

Figure 3

Successful total knee arthroplasty (TKA) depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, and adequate soft tissue balancing and stability.
It is well accepted that soft tissue imbalance and bony malalignment in TKA lead to malfunction and failure. The KNEE BALANCER was developed to assist surgeons in obtaining a well-balanced and successful total knee replacement with a simple, reproducible method. The goal is to obtain the same rectangular gap both in flexion and in extension with the same ligament tension.

This KNEE BALANCER works with the MULTIGEN PLUS Knee System only.

This technique uses conventional instruments as well as a KNEE BALANCER, a tower and dedicated 4 in 1 masks.
The surgeon employs conventional instruments to resect the distal femur and proximal tibia in his or her preferred order. The KNEE BALANCER *(Fig. 1)*, the tower *(Fig. 2)* and the 4 in 1 mask *(Fig. 3)* are then used to help balance the knee, equalize gaps in flexion and extension, set femoral extra-rotation, determine the thickness of the liner and complete the femoral resections.
The rest of the procedure is completed using standard instruments.

The following should be considered when planning to use the KNEE BALANCER Instruments:

- **The patient should have stable and functional collateral ligaments.**
- **If the patient has a varus/valgus deformity, it should be less than 20° since it is more difficult to achieve ligament balance in these patients. The deformity should be corrected first by creating a rectangular space.**
- **Ligamentous release performed in extension will also affect the flexion gap and vice versa.**
- **Bone cuts can be adjusted to create equal flexion and extension gaps. Cutting the tibia affects both flexion and extension gaps equally. Removing bone from the distal femur affects only the extension gap, while removing bone from the posterior femur affects the flexion gap only.**

KNEE BALANCER SURGICAL TECHNIQUE
Surgical Technique

INDICATIONS

The KNEE BALANCER is indicated for soft tissue balancing, in flexion and extension, and for bony alignment in total knee arthroplasty. It can be also used to determine the thickness of the MULTIGEN PLUS tibial liner and to set the femoral extrarotation.

CONTRAINDICATIONS

- Important joint instability
- Severe deficiency of collateral ligaments
- Absence of collateral ligaments
- Important bone loss on femoral or tibial joint side
- Severe varus/valgus deformity, more than 20°

Figure 4

INITIAL SETTINGS

If the knee is valgus deformed, during the medial parapatellar arthrotomy, a minimal medial takedown should be performed to the already stretched out medial ligamentous structure. If the knee has a varus deformity, an appropriate medial takedown of the tight concave structures should be initially performed.

Prior to incision, asses the knee and its ligaments to determine what adjustments might be made to the standard bony cuts. For significant flexion contracture, more distal femoral resection may be necessary. If the patient has very loose ligaments and goes into recurvatum, less distal femoral resection will be needed. Similarly, if a severe deformity exists that will require a significant concave ligamentous release, less bone resection may be required on the tibial and femoral sides to avoid large flexion/extension gaps. When making bone cuts, it is best to under-resect, as more bone can always be removed. It is important to remove posterior osteophytes early as they may effect both flexion and extension balancing.

The goal of balancing is to create a rectangular gap with the ligaments equally tensed by the balancer both in extension and in flexion. The amount of bone that should be removed from the posteromedial condyle and from the posterolateral condyle depends on the degree of pre-operative deformity and on the degree of release necessary to axially align the knee in extension.

After completing the standard distal femoral and proximal tibial resections, bring the knee into extension.

Take the balancer and turn the knobs to position the femoral paddles to an initial setting that will easily fit in the extension gap *(Fig. 4)*.

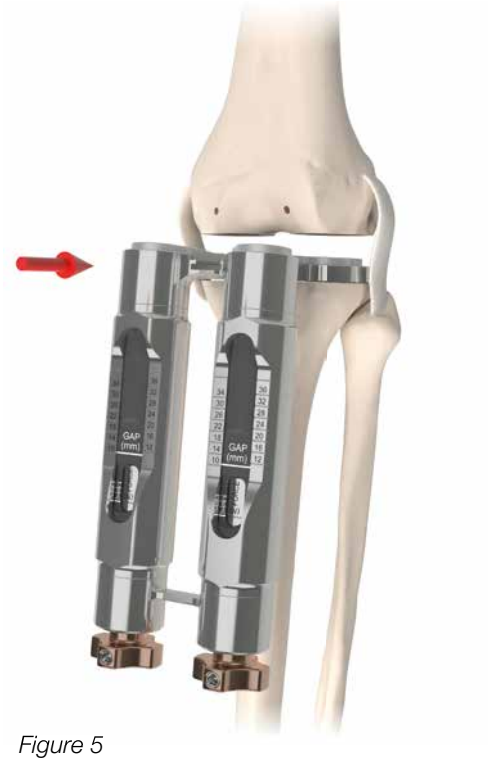
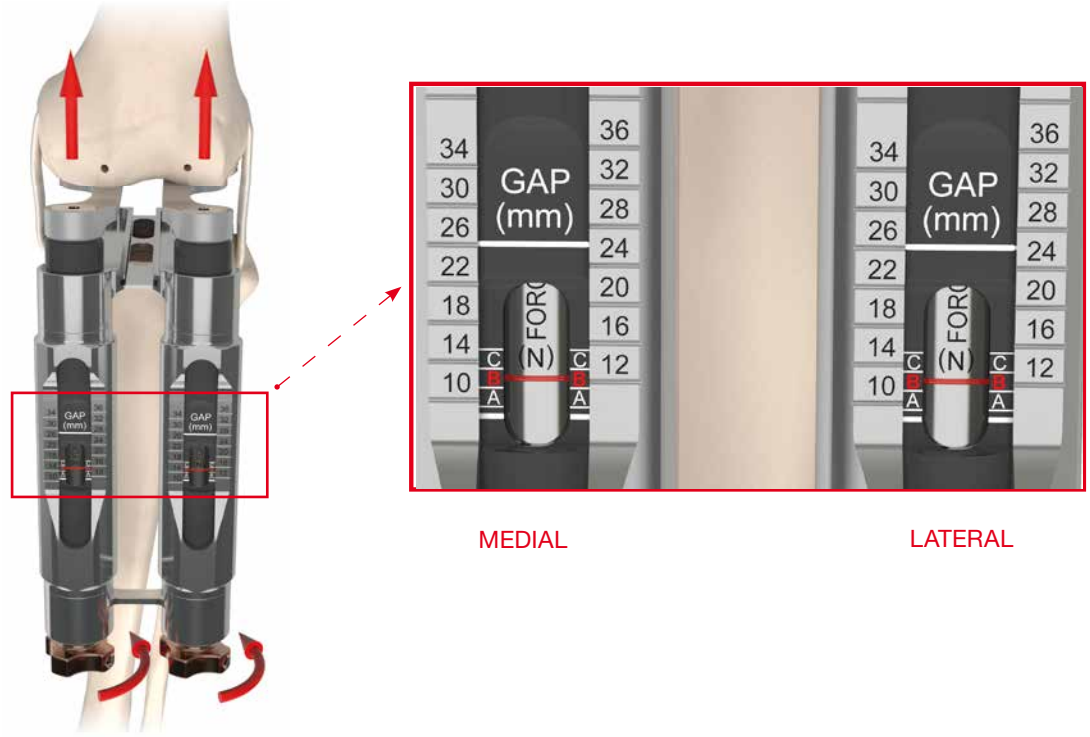


Figure 5

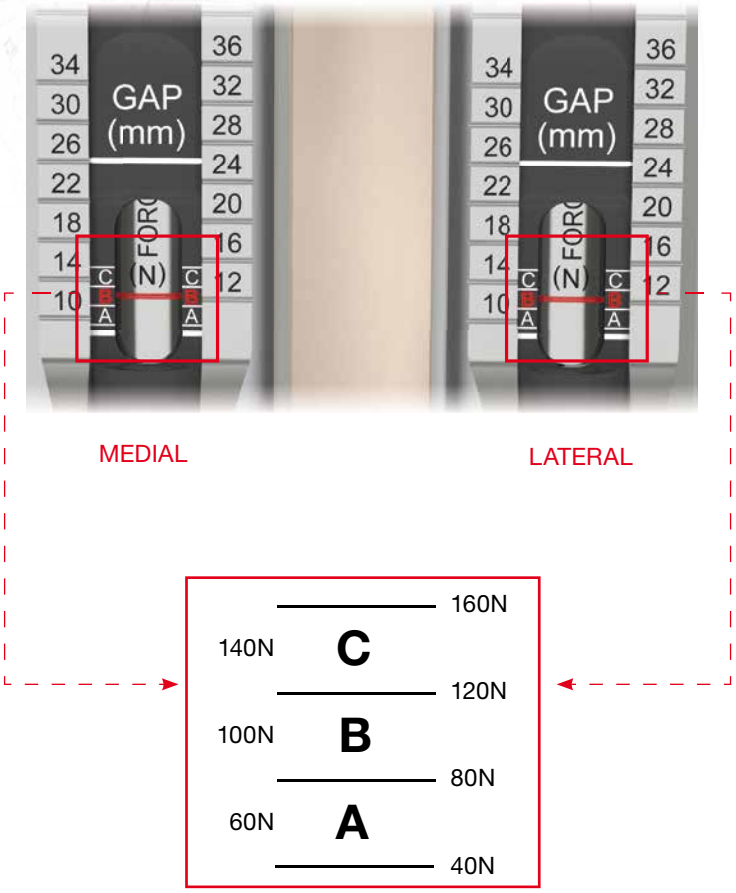
BALANCING THE EXTENSION GAP

Insert the balancer into the knee space *(Fig. 5)* so it fully engages the cut tibia and femur. It is important to place the limb in a neutral position, in order to avoid flexion or recurvatum at the knee.

Advance the paddles by turning the knobs clockwise an equal amount until the appropriate ligamentous tension is achived *(Fig. 6)*.



◆ *Figure 6*



◆ *Figure 7*

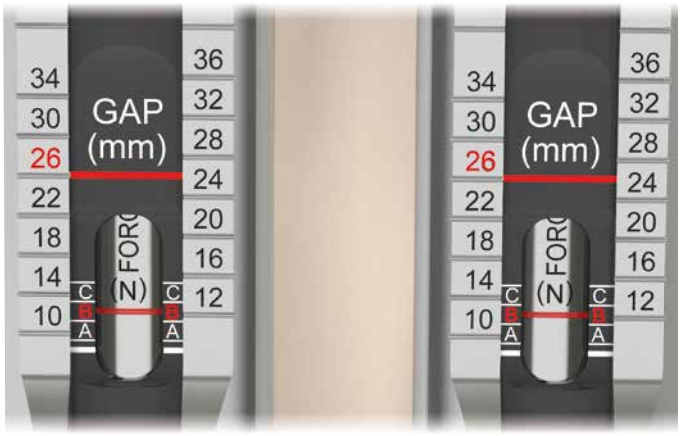
Equal tension is achieved by reaching the same setting on the joint force scale (e.g. B) on both medial and lateral part *(Fig. 7)*.

In the force scale, three primary zones are defined by letters A, B and C. Refer to section “Balancer Force Scale” for more details.

The average force in zone A is around 60 N, zone B is around 100 N and zone C is around 140 N (mark under A corresponds approximately to 40 N, mark under B corresponds approximately to 80 N, mark under C corresponds approximately to 120 N and mark upon C corresponds approximately to 160 N).

Note. *The balancer must not be used beyond zone C.*

For accurate readings from the joint scale, the paddles should only be advanced and not reduced while reading. If the balancer paddles have to be reduced during use, fully reduce then re-advance the paddles.

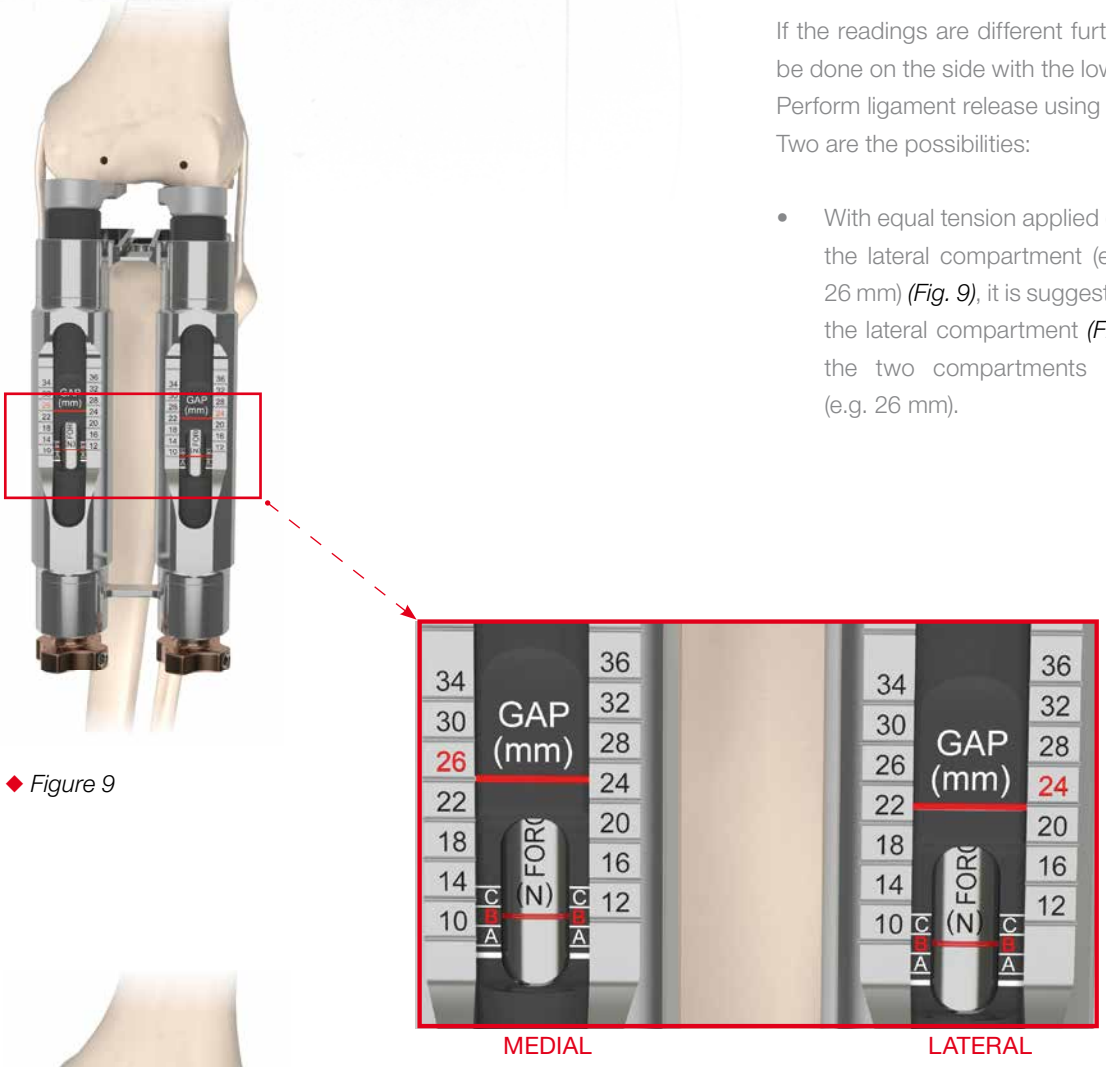


◆ *Figure 8*

Once equal tension is placed on the joint force scale (e.g. B), check the extension gap scales.
If the same reading (e.g. 26 mm) is present on the medial and lateral extension gap scale, the extension gap is rectangular *(Fig. 8)*, so the knee is balanced in extension.

Do not consider differences between the medial gap and lateral gap less than 1 mm because they are hardly evaluable and adjustable to the naked eye and in any case they do not significantly influence the final balancing.

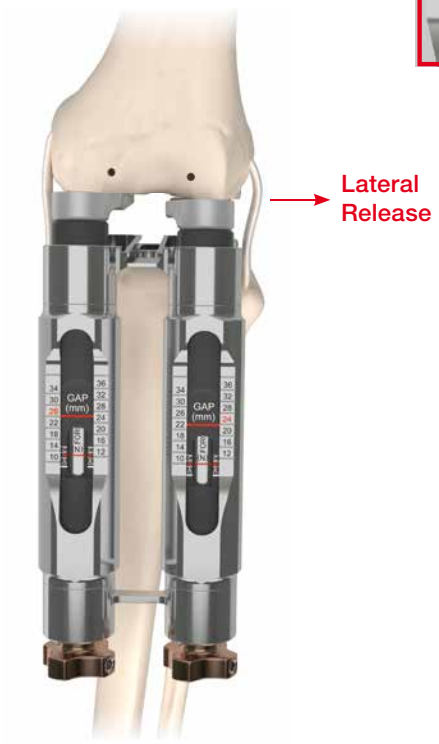
Surgical Technique



◆ *Figure 9*

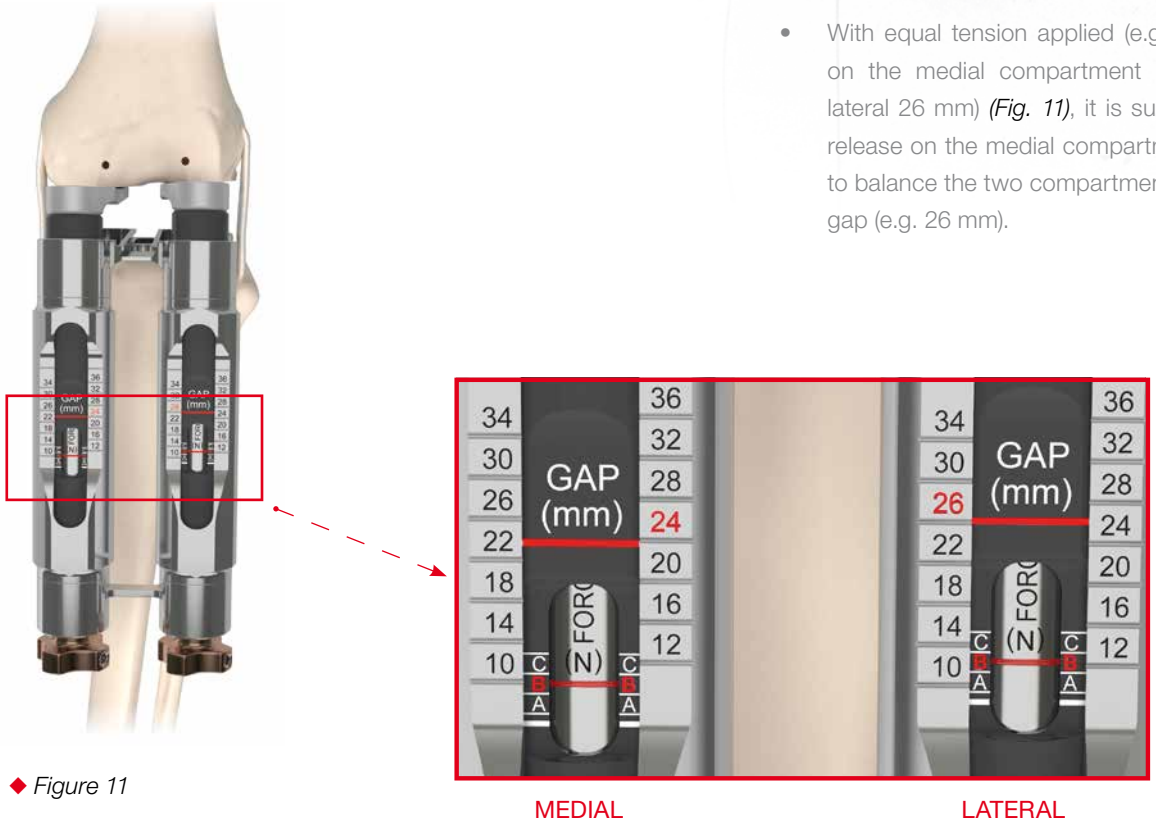
If the readings are different further ligament release must be done on the side with the lower value.
Perform ligament release using standard technique.
Two are the possibilities:

- With equal tension applied (e.g. B) and smaller gap on the lateral compartment (e.g. lateral 24 mm, medial 26 mm) *(Fig. 9)*, it is suggested to perform a release on the lateral compartment *(Fig. 10)* in order to balance the two compartments reaching the same gap (e.g. 26 mm).

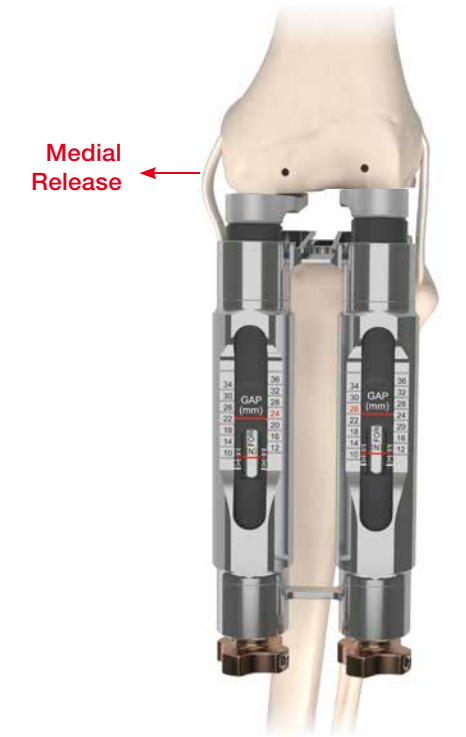


◆ *Figure 10*

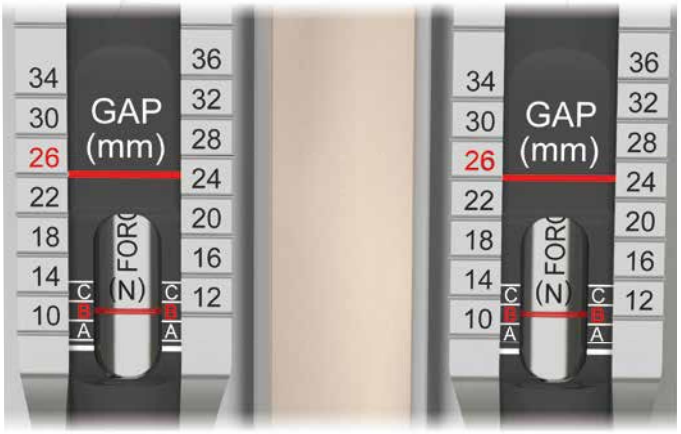
- With equal tension applied (e.g. B) and smaller gap on the medial compartment (e.g. medial 24 mm, lateral 26 mm) *(Fig. 11)*, it is suggested to perform a release on the medial compartment *(Fig. 12)* in order to balance the two compartments reaching the same gap (e.g. 26 mm).



◆ *Figure 11*



◆ *Figure 12*



MEDIAL LATERAL

◆ *Figure 13*

After further release, recheck the extension gap advancing the paddles an equal amount until the appropriate ligamentous tension (e.g. B) is achived and the same gap (e.g. 26 mm) both in medial and lateral compartment is obtained *(Fig. 13)*.

Memorize the extension gap (e.g. 26 mm) because this reading will be important for establishing the flexion gap.

Figure 14

ESTABLISHING THE FLEXION GAP AND THE FEMUR EXTRAROTATION

Once the femur size has been checked, turn the knobs to fully reduce the balancer and place the MULTIGEN PLUS flexion adapter tower into the corresponding slot in the tibial paddle *(Fig. 14)*.

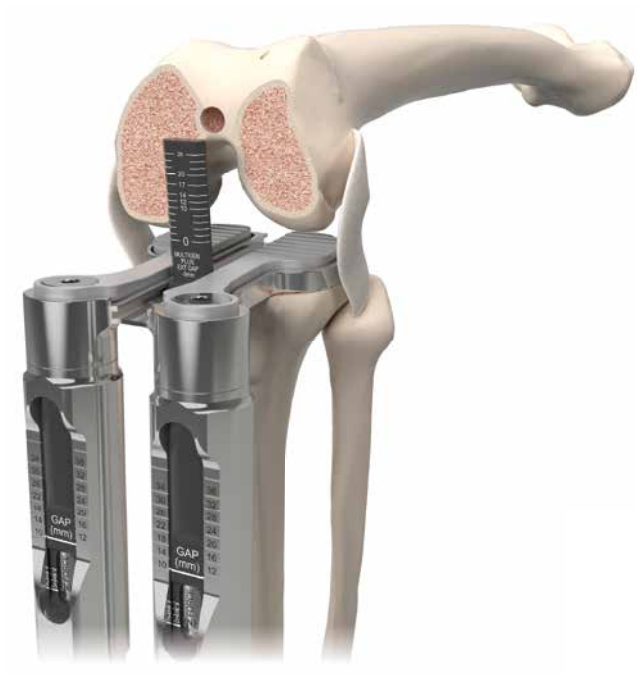


Figure 15

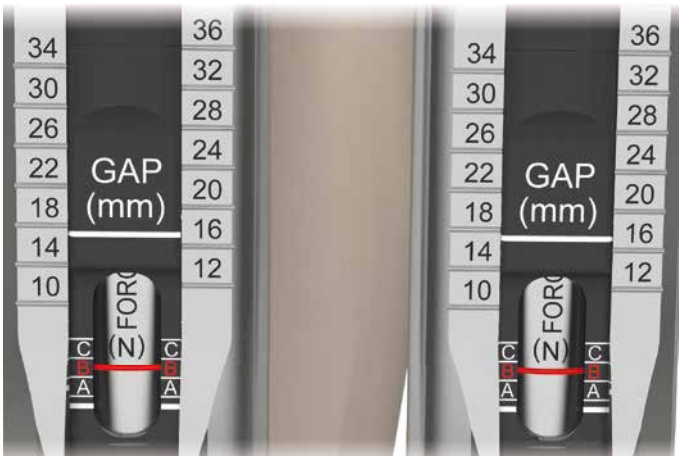
With the knee flexed precisely to 90 degrees of flexion, insert the balancer into the knee *(Fig. 15)*.

Surgical Technique

Figure 16

Turn the knobs to advance the paddles until the same tension (e.g. B) used in extension is reached, so the paddles fully engage the cut tibia and the uncut posterior condyles of the femur. The femur will now rotate to accommodate the unequal length of the previously released ligaments *(Fig. 16)*.

It is important to tense the knee to the force (e.g. B) that was used in extension, equal on both medial and lateral compartments *(Fig. 17)*.



MEDIAL LATERAL

◆ *Figure 17*

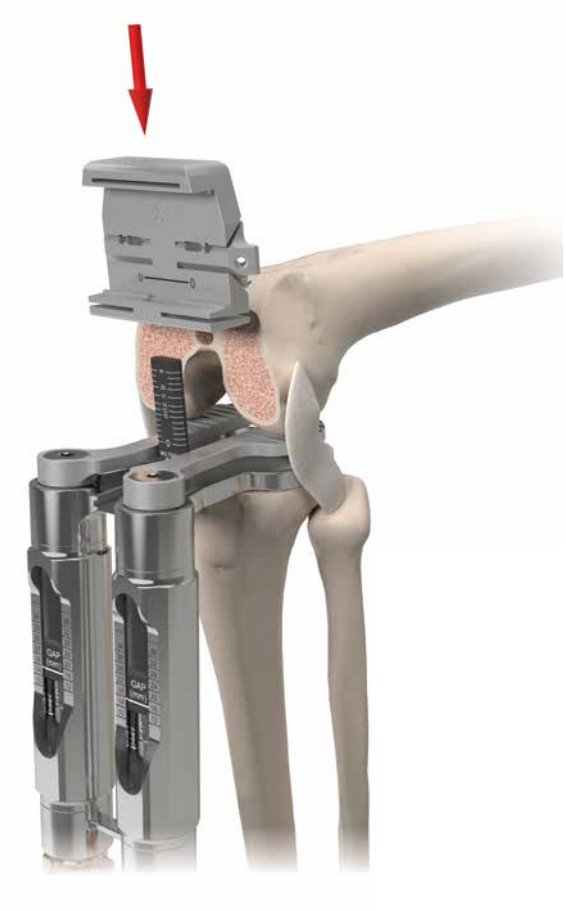


Figure 18

Position the Evolute “4 in 1” mask, of the size previously determined (e.g. #3), on the flexion adapter tower *(Fig. 18)*. The flexion adapter tower is used to position the “4 in 1” mask parallel to the tibia when ligaments are equally tensed.

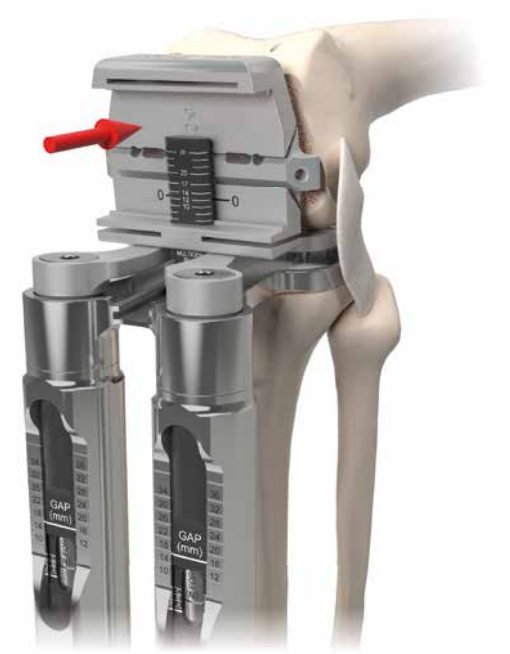
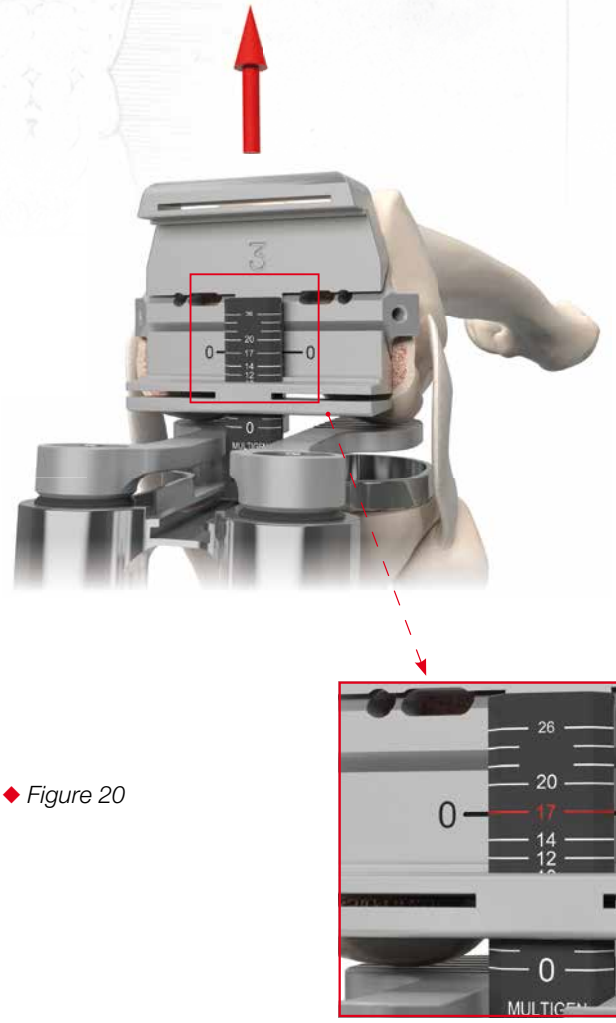


Figure 19

Move the mask and the tower posteriorly until they come into contact with the cut distal surface *(Fig. 19)*.



◆ *Figure 20*

Slide the mask up *(Fig. 20)* until the "0" mark on the mask is flush with the mark on the tower corresponding to the measure in millimetres previously noted in extension decreased of 9 mm (e.g. 26 mm - 9 mm = 17 mm). 9 mm is the thickness of the femoral posterior condyles (constant value for all sizes), the scale of the tower takes already into consideration this thickness.

If ligaments are equally tensed by the balancer both in extension and in flexion and the "4 in 1" mask is positioned through the tower, the correct extrarotation of the femur is automatically assured.

Example:

17	**=**	**26**	**-**	**9**
Liner thickness		Extension gap		Posterior condyles thickness

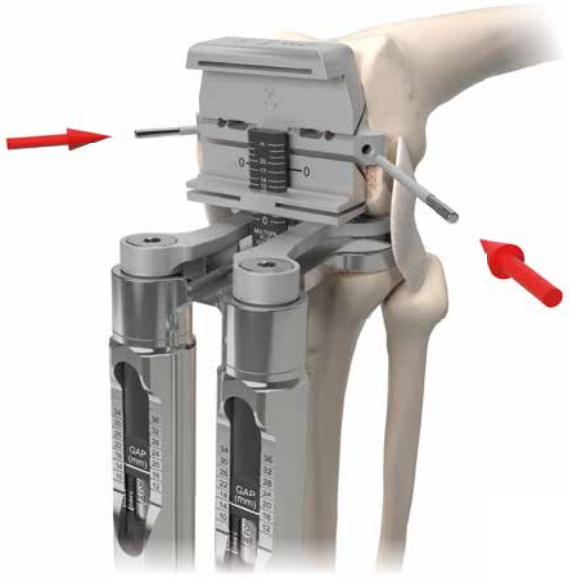


Figure 21

Once the reading on the tower matches the previously measured extension gap decreased of 9 mm (e.g. 17 mm), fix the "4 in 1" mask with two pins into the lateral angled holes *(Fig. 21)*.

This measure (extension gap decreased of 9 mm, e.g. 26 mm - 9 mm = 17 mm) will correspond to the thickness of the MULTIGEN PLUS liner (e.g. 17 mm) that will have to be used.

Note. *The thicknesses of the MULTIGEN PLUS liners are: 10-12-14-17-20 mm.*

Turn the knobs to fully reduce the balancer *(Fig. 22)* and remove first anteriorly the balancer and then downwards the tower *(Fig. 23)*.

Figure 22

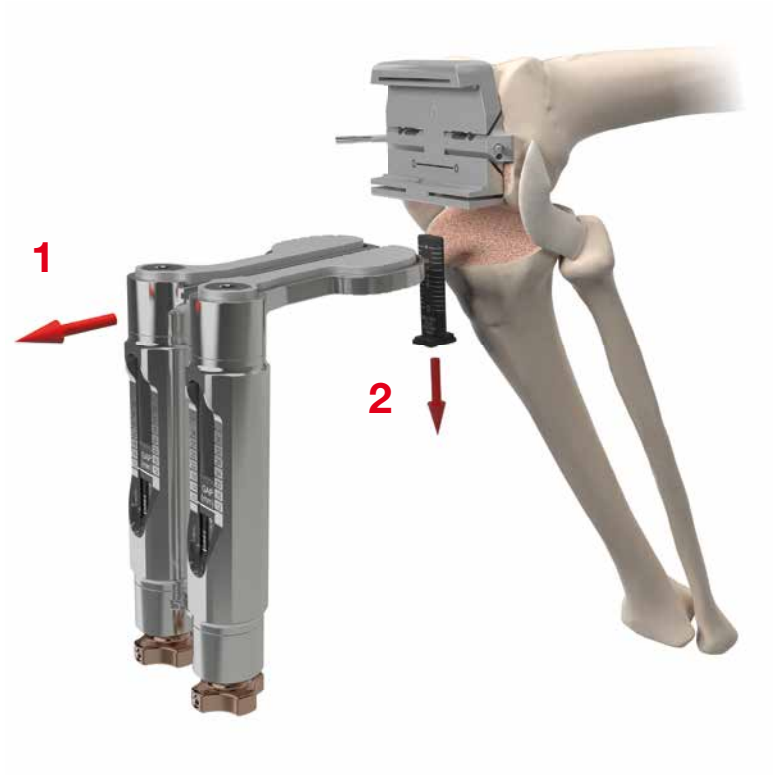


Figure 23

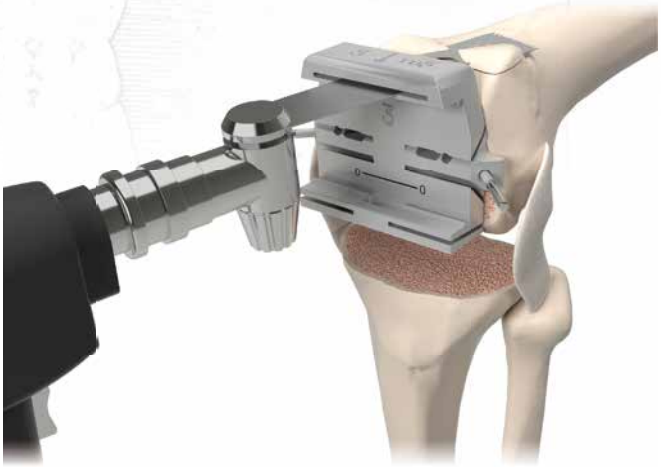


Figure 24

Proceed performing the anterior *(Fig. 24)*, posterior *(Fig. 25)*, anterior oblique *(Fig. 26)* and posterior oblique *(Fig. 27)* resections.

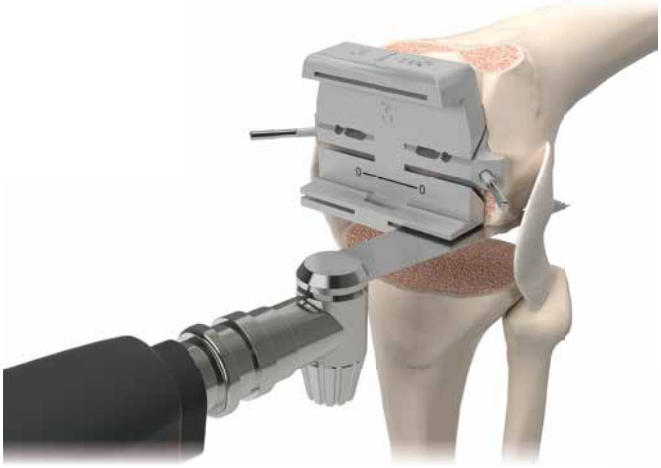


Figure 25

Figure 26

Figure 27

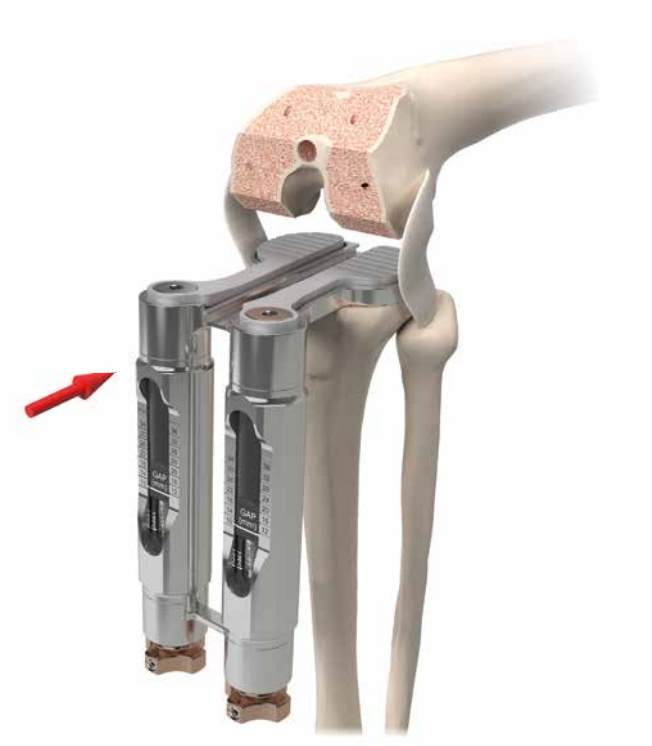
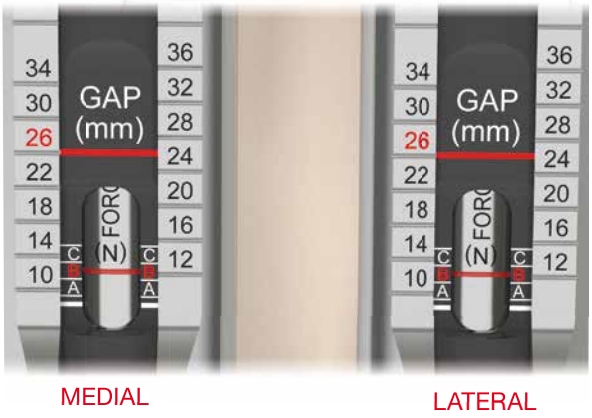


Figure 28

Once all the femoral resections have been performed it is possible to check the flexion gap with the cut posterior condyles.
Take the balancer and turn the knobs to position the femoral paddles to an initial setting that will easily fit in the flexion gap. Insert the balancer into the knee *(Fig. 28)* so it fully engages the cut tibia and femur.

Figure 29

Advance the paddles by turning the knobs clockwise an equal amount until the appropriate ligamentous tension is achived *(Fig. 29)*.



◆ *Figure 30*

Equal tension is achieved by reaching the same setting on the joint force scale on both medial and lateral part. Check on the force scale if the force applied to reach equal tension is the same of the one that was applied in extension (e.g. B) and check if the the flexion gap (e.g. 26 mm) that can be read on the gap scale, both on the medial and on the lateral side) corresponds to the extension one previous determined and to the flexion one measured before the posterior cut *(Fig. 30)*.

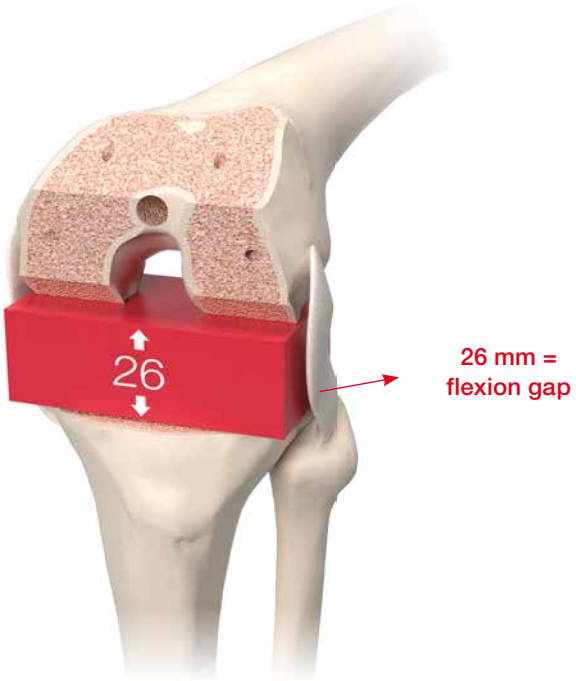


Figure 31

So if the same rectangular gap (e.g. 26 mm), with the ligaments equally tensed (e.g. B), has been created, both in extension *(Fig. 31)* and in flexion *(Fig. 32)*, the result is a balanced knee with correct extrarotation and equal gap.

The minimum gap both in flexion and in extension is 19 mm (gap: 19, 21, 23, 26, 29 mm).

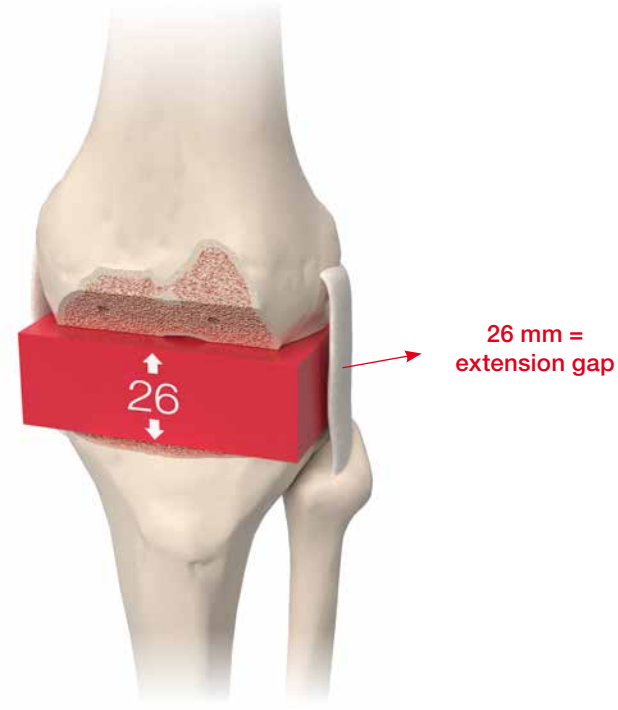


Figure 32

If the definitive implant will be a cemented one, remember to take into consideration the thickness of the cement of 1 mm for the tibia and 1 mm for the femur. So the gap should be 21 mm as a minimum (gap: 21, 23, 25, 28, 31 mm) both in flexion and in extension.

NOTE

Distal Thickness = 9 mm

Posterior Condyles Thickness = 9 mm

Tibial Thickness =
- 10 mm (2 mm Plate, 8 mm Liner)
- 12 mm (2 mm Plate, 10 mm Liner)
- 14 mm (2 mm Plate, 12 mm Liner)
- 17 mm (2 mm Plate, 15 mm Liner)
- 20 mm (2 mm Plate, 18 mm Liner)

Extension gap = Distal (9 mm) +
Tibial (10, 12, 14, 17, 20 mm) =
19, 21, 23, 26, 29 mm

Flexion gap (with posterior cut) = Posterior Condyle (9 mm) + Tibial (10, 12, 14, 17, 20 mm) = 19, 21, 23, 26, 29 mm

KNEE BALANCER SURGICAL TECHNIQUE

Flexion/Extension Gap Balancing

The following table shows the different scenarios that can occur during the balancing of the knee and suggests for each of them a possible solution to be adopted.

	LOOSE EXTENSION	TIGHT EXTENSION	STABLE EXTENSION
LOOSE FLEXION	• Thicker tibial liner	• Recut distal femur • Posterior capsular release • Larger femoral component	• Decrease tibial slope and use a thicker tibial liner • Recut distal femur and use a thicker tibial liner • Larger femoral component
TIGHT FLEXION	• Check for osteophytes • Downsize femoral component • Increase tibial slope (CR only)	• Thinner tibial liner • Recut tibia	• Check for osteophytes • Downsize femoral component • Increase tibial slope (CR only)
STABLE FLEXION	• Downsize femoral component • Increase tibial slope (CR only) and use a thicker tibial liner	• Recut distal femur • Posterior capsular release • Larger femoral component	Balanced Gaps

Balancer Instrument Assembly

Figure 33

The balancer can be disassembled to allow a proper washing and sterilization of each part.

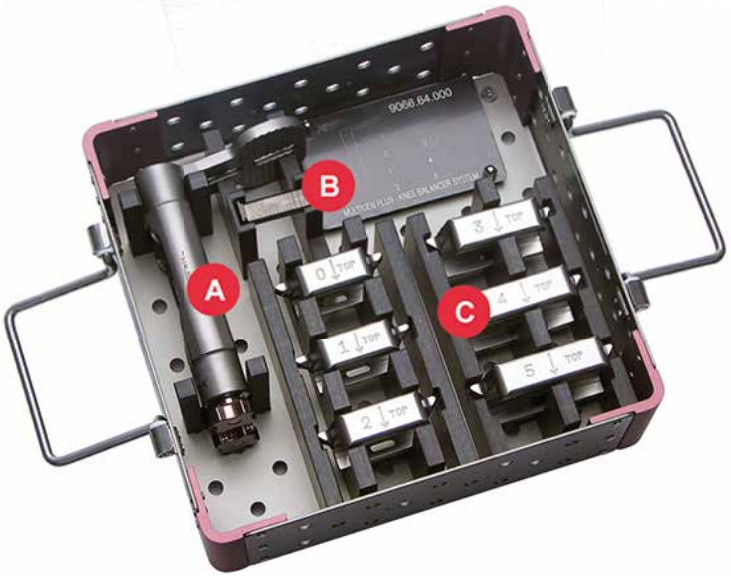
It is suggested to adopt the following correct procedure:

1. Disassemble the balancer removing the paddles from the body of the balancer. Take the balancer and advance the paddles by turning the knobs clockwise *(Fig. 33)* until the paddles come out completely from the body of the balancer *(Fig. 34).*
2. Wash separately the instrument parts.
3. Sterilize separately the instrument parts.
4. Once all the instrument parts have been washed and sterilized, re-assemble the balancer repositioning the paddles into their seat. Take the body of the balancer and introduce in it the paddles by turning the knobs counterclockwise until the paddles are completely inserted into the body.

Figure 34

KNEE BALANCER SURGICAL TECHNIQUE
Instrument Set

9066.64.000 KNEE BALANCER System Set



CODE	Ref.	DESCRIPTION	Qt.
9066.64.010	A	Balancer	1
9066.64.020	B	Tower	1
9066.64.100	C	45° Resection Guide - #0	1
9066.64.110	C	45° Resection Guide - #1	1
9066.64.120	C	45° Resection Guide - #2	1
9066.64.130	C	45° Resection Guide - #3	1
9066.64.140	C	45° Resection Guide - #4	1
9066.64.150	C	45° Resection Guide - #5	1
9066.64.950		Sterilizable Box	1

BALANCER FORCE SCALE

The force scale on the KNEE BALANCER ranges from 40N to 160N and is divided into three primary zones, defined by letters A, B and C, to accommodate different balancing philosophies. Depending which range force is chosen it is important to realize the trade-offs.

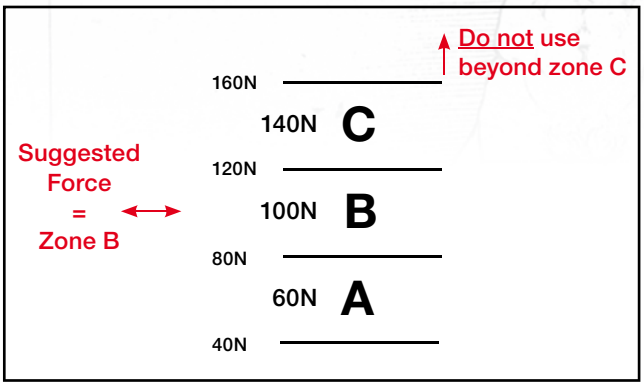
The average force in zone A is around 60 N, zone B is around 100 N and zone C is around 140 N (mark under A corresponds approximately to 40 N, mark under B corresponds approximately to 80 N, mark under C corresponds approximately to 120 N and mark upon C corresponds approximately to 160 N).

Note. *The balancer must not be used beyond Zone C.*

Choosing Zone A it is likely to have:
- good prediction of the liner thickness
- not excessive femoral rotation
- increased discrepancy between flexion and extension forces due to the weight of the femur

Choosing Zone C it is likely to have:
- magnification of any imbalance of the knee
- less error induced by the weight of the femur
- increased femoral rotation

When balancing in flexion, the weight of the thigh can have a small influence on the accuracy of the balancer. Based on anthropometric data, it is calculated that 3.1% of the body weight is supported by the balancer during flexion, while very little body weight is supported in extension [1, 2]. For the average patient of 75 kg, it is calculated that about 2,3 kg (22,5 N) counteracts the forces applied by the balancer. Literature suggests this could lead to a slight (0,3 to 0,7 mm) over-resection of the posterior condyles [3]. Manually elevating the thigh can help, paying attention not to rotate the femur and not to suspend the lower leg.



Note. *Only advance and never reduce the paddles when reading forces during use.*

When tensing the knee, a frictional force inside the balancer adds to the joint force read on the scale.
This frictional force is accounted for in the markings.
However, when the balancer is being reduced the frictional forces reverse direction and can decrease the accuracy of the instrument's force reading. Therefore, it is highly recommended only to advance the paddles and never reduce the paddles when reading forces during use.

BALANCER CALIBRATION

It is highly recommended to send back the balancer to Lima Corporate every 6 months or every 100 surgeries to check if the calibration of the instrument has been maintained or if it is necessary to recalibrate it in order to guarantee a precise and accurate functioning both in terms of measurement of forces and in terms of measurement of the gap.

[1] Winter DA. "Biomechanics and Motor Control of Human Movement". John Wiley & Sons, Inc. New York, 1990.
[2] Ross B. "A biomechanical model for estimating moments of force at hip and knee joints in the barbell squat". October 2006
[3] Fiskin Z. et al. "Changes in human knee ligament stiffness secondary to osteoarthritis". J. Orthop Res. 204, 2002.

Lima Corporate
Orthopaedic motion

Limacorporate spa
Via Nazionale, 52
33038 Villanova di San Daniele
Udine - Italy
Tel.: +39 0432 945511
Fax: +39 0432 945512
E-mail: info@limacorporate.com
www.limacorporate.com

Lima Implantes slu
Fontsanta, 46 5ª planta
08970 Sant Joan Despí - Barcelona
Tel.: 93 480 85 05
Fax: 93 419 65 27

Lima France sas
Les Espaces de la Sainte Baume
Parc d' Activité de Gémenos - Bât.A5
30 Avenue du Château de Jouques
13420 Gémenos - France
Tel: +33 (0) 4 42 01 63 12
Fax:. +33 (0) 4 42 04 17 25
E-mail: info@limafrance.com

Lima O.I. doo
Ante Kovacic, 3
10000 Zagreb - Croatia
Tel.: +385 (0) 1 2361 740
Fax: +385 (0) 1 2361 745
E-mail: lima-oi@lima-oi.hr

Lima Switzerland sa
Birkenstrasse, 49
CH-6343 Rotkreuz - Zug
Switzerland
Tel.: +41 (0) 41 747 06 60
Fax: +41 (0) 41 747 06 69
E-mail: info@lima-switzerland.ch

Lima Japan kk
Shinjuku Center Building, 29th floor
1-25-1, Nishi-shinjuku, Shinjuku,
Tokyo 163-0629 - Japan
Tel.: +81 3 5322 1115
Fax: +81 3 5322 1175

Lima CZ sro
Do Zahrádek I., 157/5
155 21 Praha 5 – Zličín –
Czech Republic
Tel.: +420 222 720 011
Fax: +420 222 723 568
E-mail: info@limacz.cz

Lima Deutschland GmbH
Kapstadtring 10
22297 Hamburg - Germany
Tel.: +49 40 6378 4640
Fax: +49 40 6378 4649
E-mail: info@lima-deutschland.com

Lima Austria GmbH
Ignaz–Köck–Strasse 10 / Top 3.2
1210 Wien - Austria
Tel.: +43 (1) 2712 469
Fax: +43 (1) 2712 469 100
E-mail: info@lima-austria.at

Lima SK s.r.o.
Zvolenská cesta 14
97405 Banská Bystrica - Slovakia
Tel.: +421 484 161 133
Fax: +421 484 161 138
E-mail: info@lima-sk.sk

Lima Netherlands
Havenstraat 30
3115 HD Schiedam
The Netherlands
Tel.: +31 (0) 10 246 26 60
Fax: +31 (0) 10 246 26 61
info@limanderland.nl
www.limanederland.nl

Lima Implantes Portugal S.U. Lda
Rua Olavo D'Eça Leal Nº6 Loja-1
1600-306 Lisboa - Portugal
Tel : +35 121 727 233 7

Lima Orthopaedics Australia Pty Ltd
Unit 1, 40 Ricketts Rd
Mt Waverley 3149
Victoria Australia
Tel.: +61 (03) 9550 0200
Fax: +61 (03) 9543 4003
www.limaortho.com.au

Lima Orthopaedics New Zealand Ltd
Zone 23, Unit 102, Edwin Street, Mt Eden
Auckland 1024
New Zealand
Tel.: +64 (09) 531 5522
Fax: +64 (09) 522 3380

Lima Orthopaedics UK Limited
The Pavillon, Campus 5, Unit 1
Third Avenue
Letchworth Garden City
Hertfordshire SG6 2JF
United Kingdom
Tel.: +44 08 45833 4435
Fax: +44 08 45833 4436

Lima USA Inc.
2106 W. Pioneer Parkway, Suite 126
Arlington, TX 76013
Tel.: +1 817-342-0240 / 800-962-2578
Fax: +1 817-342-0241 / 800-962-2579

Lima Sweden AB
Företagsallén 14 B
SE-184 40 ÅKERSBERGA
Sweden
Tel.: +46 8 544 103 87
Fax: +46 8 540 862 68
www.linksweden.se

Lima Italy
Centro Direzionale Milanofiori
Strada 1 – Palazzo F1
20090 Assago - Milano - Italy
Tel.: +39 02 57791301

Hit Medica spa
Strada Borrana 38
47899 Serravalle, Republic of San Marino
Tel.: +378 0549 961911
Fax: +378 0549 961912
E-mail: info@hitmedica.com

www.limacorporate.com

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