



**SPACEFLEX**  
HIP



**SPACEFLEX**  
KNEE



**SPACEFLEX**  
SHOULDER

**FUTURE IS FLEX**

**G21**  
STRENGTH FOR LIFE

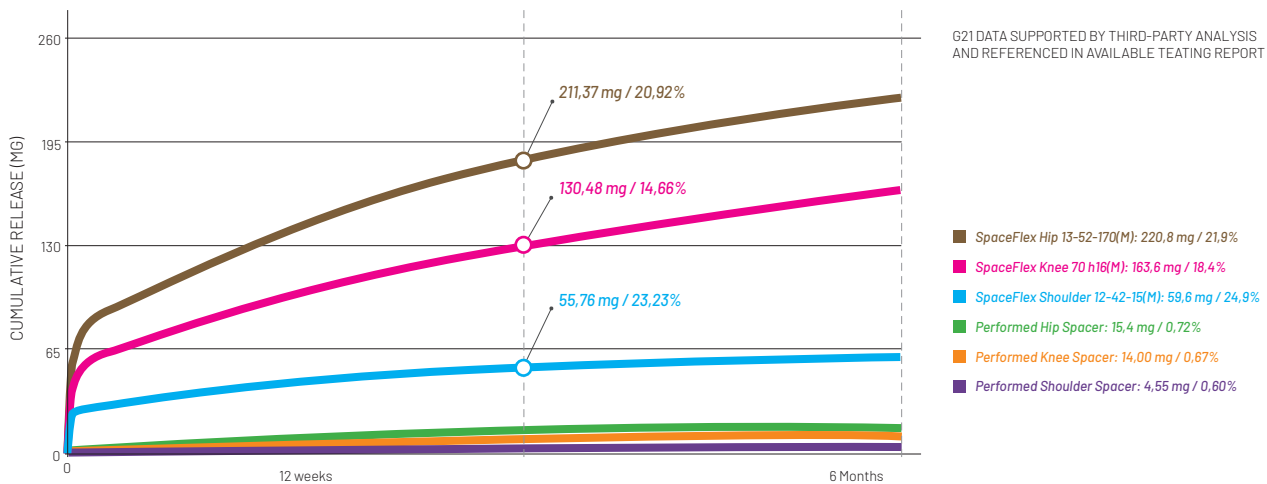


**SPACEFLEX**

The G21's low viscosity bone cement (G3 and G3A bone cements) with its low polymerization temperature, combined with the design of SpaceFlex mold for Hip, Knee and Shoulder, supports the surgeons in selecting an effective and customized solution in terms of modularity and antibiotic activity.

Compared to Preformed systems, SpaceFlex molds are developed to combine different antibiotics, granting a constant and high level of elution.

## ANTIBIOTIC RELEASE OVER TIME COMPARISON

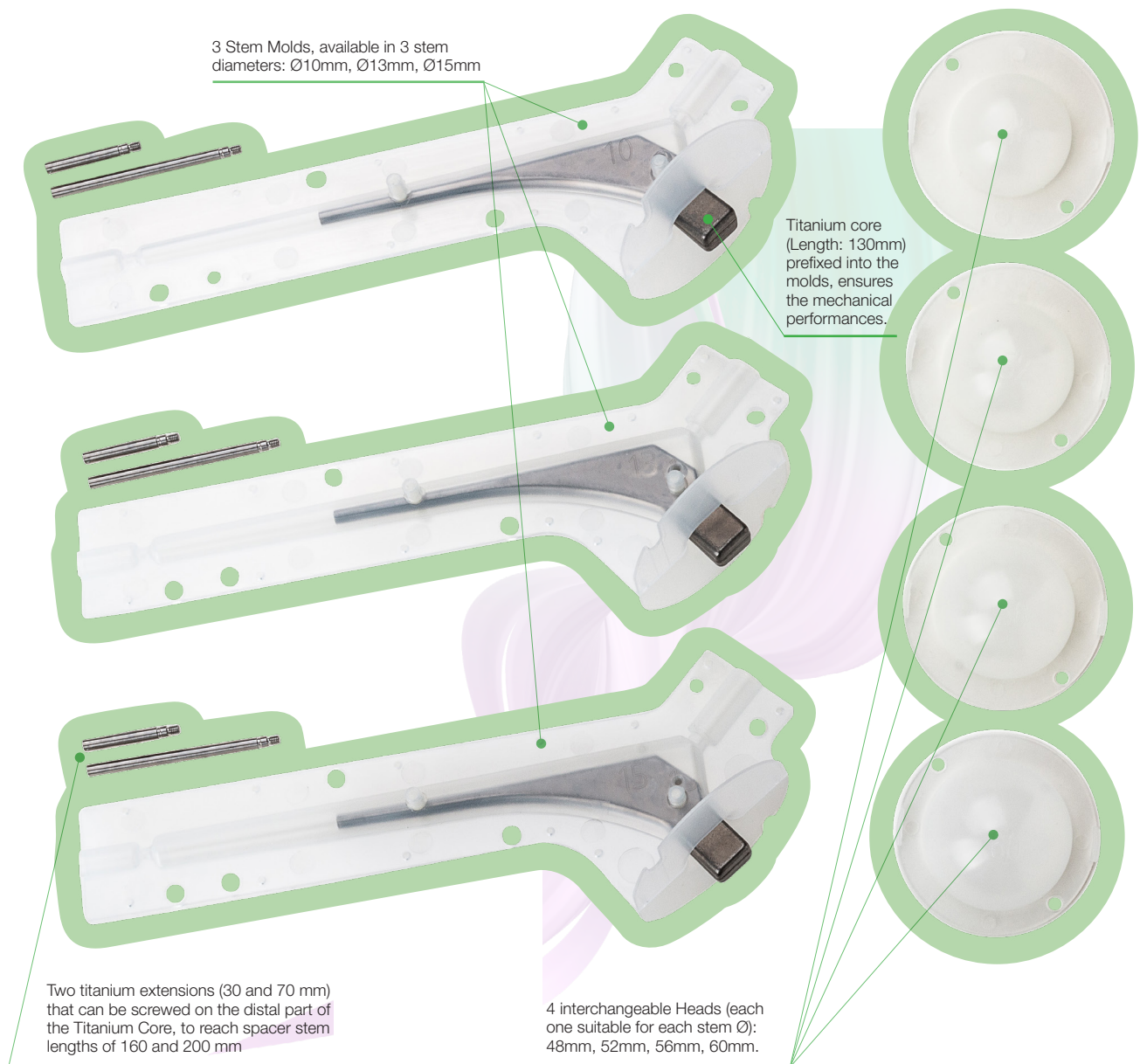


G21 carries out an in vitro study [1] with the aim of evaluating the mechanical and elution properties of G3 Bone Cement loaded with different doses of up to three antibiotics (12 specimens). The results obtained in this pilot study using G3 Bone Cement, demonstrated that mechanical properties do not decrease significantly by adding large doses of antibiotics, while the Vancomycin elution increase until swelled to twice.

# SPACEFLEX HIP - MODULARITY

HANDY and EASY customization between disposable molds and reusable Instrument Kit conceived to obtain a Monoblock Spacer, with a single bone cement injection phase [2]. Up to 36 available configurations of spacer realizable in OR:

## 3 STEMS DIAMETER X 3 STEMS LENGTH X 4 ACETABULAR HEAD DIAM



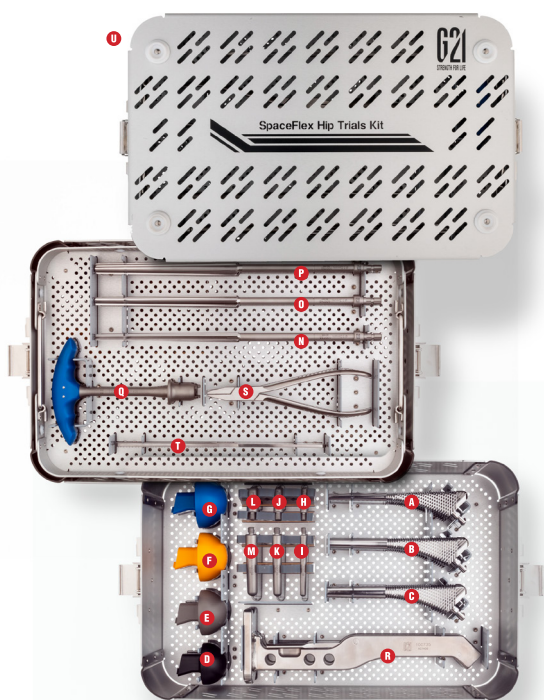


# SPACEFLEX HIP - MODULARITY

Molds Required to be assembled in a reusable instrument kit.



A set of trials is available, to offer the surgeon the possibility to prepare the patient's anatomical site and realize the most suitable spacer dimension:



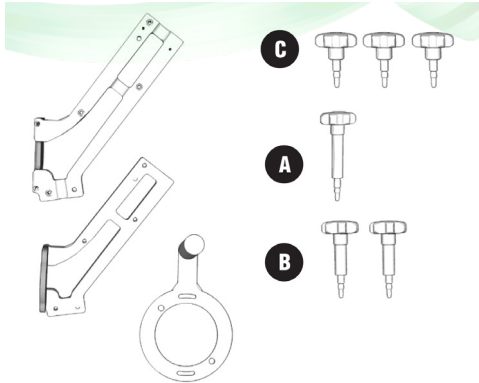
Identification letter	Description	Q.TY
A	SpaceFlex Hip Trial Broach Ø10 mm	1
B	SpaceFlex Hip Trial Broach Ø13 mm	1
C	SpaceFlex Hip Trial Broach Ø15 mm	1
D	SpaceFlex Hip Trial Head Ø48 mm	1
E	SpaceFlex Hip Trial Head Ø52 mm	1
F	SpaceFlex Hip Trial Head Ø56 mm	1
G	SpaceFlex Hip Trial Head Ø60 mm	1
H	SpaceFlex Hip Broach Extension S Ø10mm	1
I	SpaceFlex Hip Broach Extension L Ø10mm	1
J	SpaceFlex Hip Broach Extension S Ø13mm	1
K	SpaceFlex Hip Broach Extension L Ø13mm	1
L	SpaceFlex Hip Broach Extension S Ø15mm	1
M	SpaceFlex Hip Broach Extension L Ø15mm	1
N	Conical Reamer Ø10mm	1
O	Conical Reamer Ø13mm	1
P	Conical Reamer Ø15mm	1
Q	T-Handle	1
R	Broach Handle	1
S	Plier	1
T	Rasp	1
U	SpaceFlex Hip Trial! Tray	1



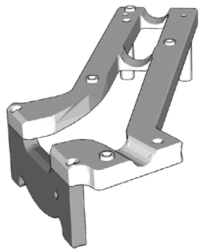
# SPACEFLEX

# HIP SPACER REALIZATION

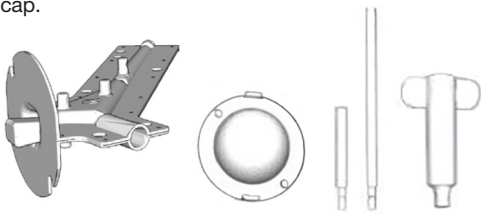
- 1** Once sterilization is performed, extract all components of the SpaceFlex Hip Instrument Kit.



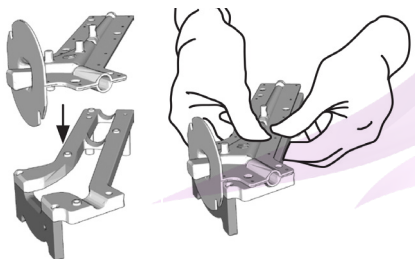
- 2** Place the lower part horizontally on its base.



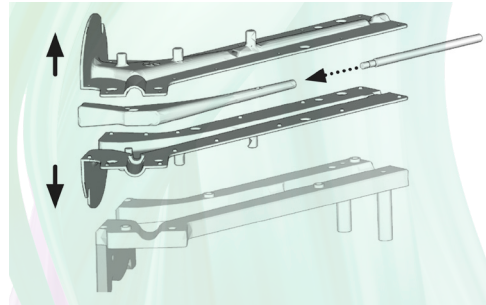
- 3** Remove from the sterile packaging the components for making the spacer: blister couplet with centered core, the femoral head blister, extension for the titanium core, cap.



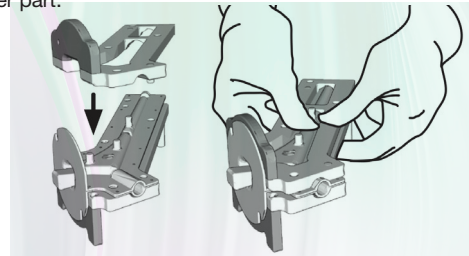
- 4** Insert the couplet into the stem blister, with the core centered using the centering spinets, in the lower part of the Instrument Kit.



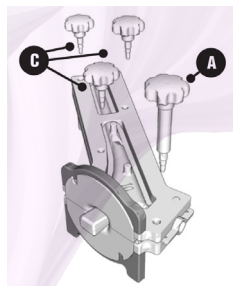
- 5** If necessary open the stem blister couplet to screw one of the two extensive extensions to the core, removing it from the lower part of the blister, and repositioning it once done;  
NOTE: When opening, carefully remove the components, taking care not to break the centering spinets.



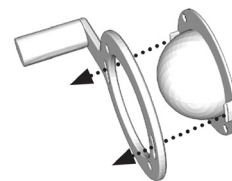
- 6** Position the upper part of the Instrument Kit onto the lower part.



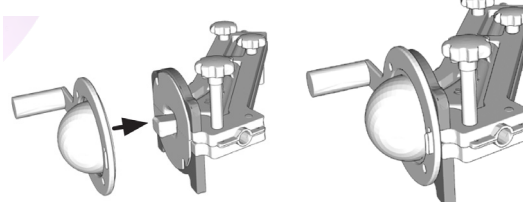
- 7** Close the instrument by screwing "C" and "A" screws.



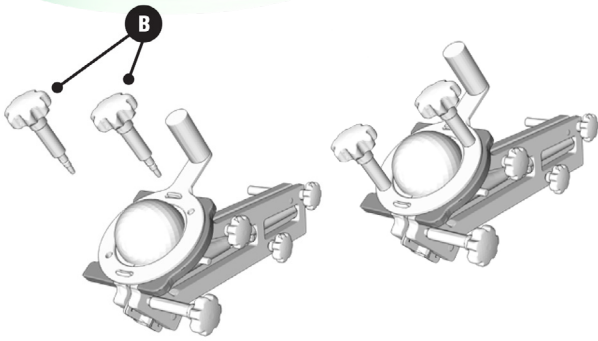
- 8** Following the surgeon's instructions, select the size of the femoral head most suited to the patient's anatomy and insert it into the femoral head casing of the Instrument Kit.



- 9** Position the blister-casing system into the cutting position, and position the casing for the femoral heads, aligning the holes for insertion of the screws.

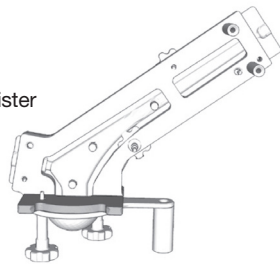


- 10** Close the system by screwing the “B” screws, and taking care that the stabilization pin is positioned toward the part of the stem, to keep the instrument in a vertical position suited to use.



- 11** Check that all of the screws have been screwed correctly.

- 12** Position the instrument-blister vertically.

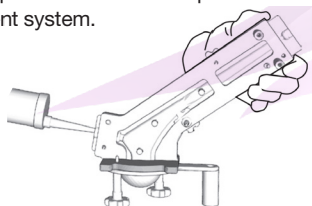


- 13** Prepare the bone cement following the manufacturer's instructions.

Hip Spacer Available Sizes	Recommended G3/G3A Bone Cement units #No.
Stem 10 - all 12 different configurations	3
Stem 13 - all 12 different configurations	3
Stem 15 - all 12 different configurations	3

Warning: the amounts given above were measured considering the use of G3/G3A bone cement and the PicoMix Syringe mixing device - note that the volume of other bone cements may change the amount of bone cement to use to correctly fill the SpaceFlex Hip molds.

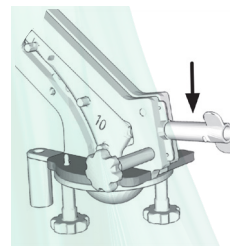
- 14** Connect the injection system to the mixing device and insert the spout inside the canal present in the blister-instrument system.



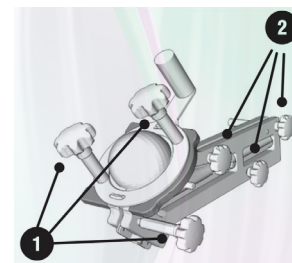
- 15** Following the cement manufacturer's timing instructions, start the injection phase, injecting slowly and constantly to minimize formation of air bubbles, the leakage or deformation of the spacer.

- 16** Stop the injection phase once the desired stem length is reached, indicated by the lines on the instrument (130 - 160 - 200 mm).  
Note: Pay close attention to cover the reinforcement stem with cement and any extensions connected thereto.

- 17** Remove the injection system from the canal and insert the included cap to prevent cement leakage.

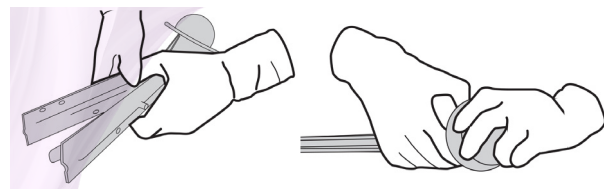


- 18** Await complete polymerization of the cement.

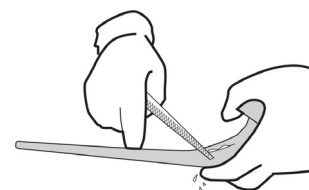


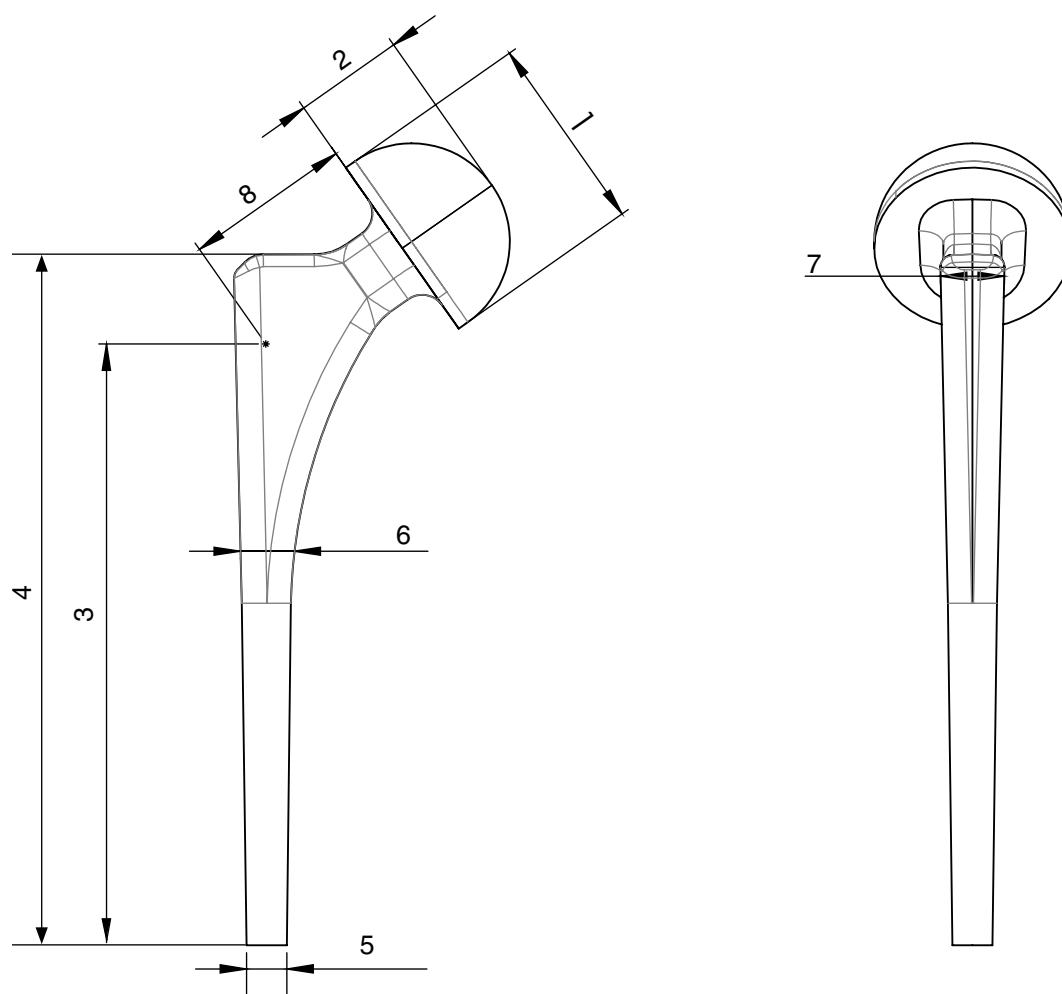
- 19** Once polymerized, disassemble the instrument, unscrew the screws, starting from the head casing and then the stem part.

- 20** Once the blister system that composed it is released, remove the spacer, taking advantage of the flexibility of these parts compared to the bone cement.



- 21** Once removed, refinish the contours of the spacer, removing any excess residues (spinet centering residues and any excess cement).





MM

Description	1	2	3	4	5	6	7	8
Head 48	48,0	27,0						
Head 52	52,0	29,0						
Head 56	56,0	31,0						
Head 60	60,0	33,0						
Stem Ø 10 - Stem Length 130			135	154,5	8,5	11,3	14,0	44,0
Stem Ø 10 - Stem Length 160			170	184,5	7,6	11,3	14,0	44,0
Stem Ø 10 - Stem Length 200			210	224,5	6,5	11,3	14,0	44,0
Stem Ø 13 - Stem Length 130			135	154,5	11,4	14,3	16,9	44,0
Stem Ø 13 - Stem Length 160			170	184,5	10,6	14,3	16,9	44,0
Stem Ø 13 - Stem Length 200			210	224,5	9,5	14,3	16,9	44,0
Stem Ø 15 - Stem Length 130			135	154,5	13,4	16,3	18,9	44,0
Stem Ø 15 - Stem Length 160			170	184,5	12,6	16,3	18,9	44,0
Stem Ø 15 - Stem Length 200			210	224,5	11,5	16,3	18,9	44,0



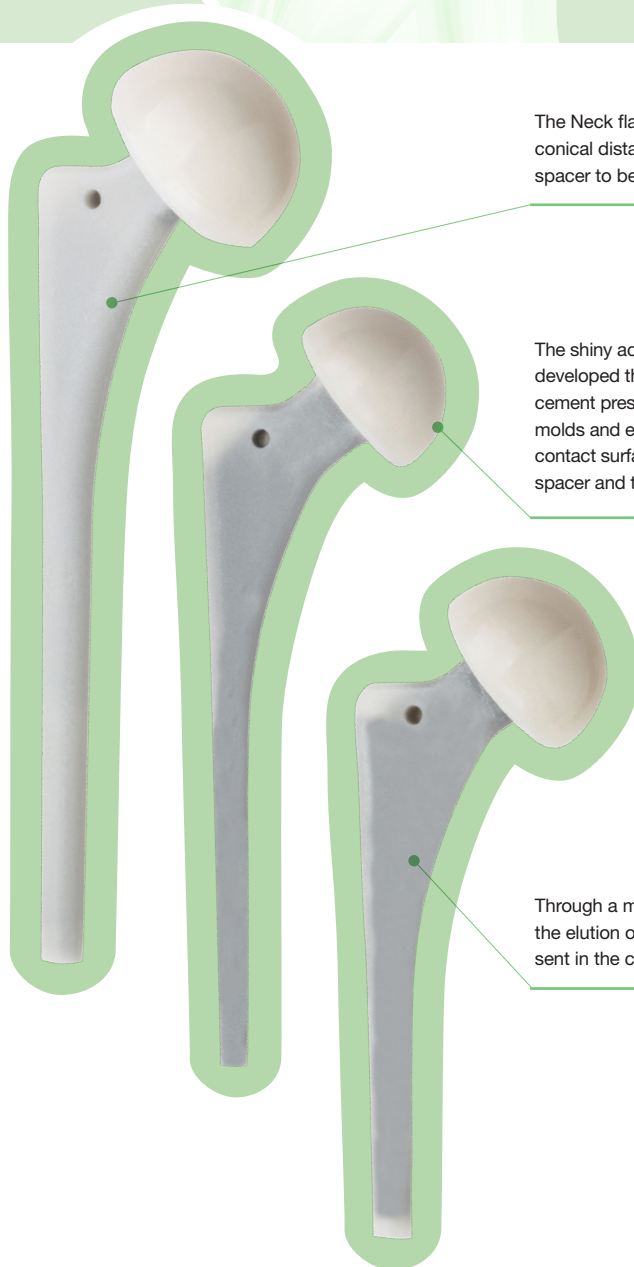
# SPACEFLEX

# HIP - THE SPACER

The combination between G21 bone cement and SpaceFlex Hip mold ensures a smooth contact surface between the femoral head and acetabular cavity by minimizing the friction during motion [2].

Femoral head and stem design enhance safety mobility allowing an anatomical press fitting and persevering the tensioning of the soft tissue.

The material and design of titanium core reinforcement guarantees a high level of safety in mechanical resistance of the spacer in compliance with the international of standard for Implants for surgery [2, 3].



The Neck flat area and the conical distal stem ensures the spacer to be positioned Presfitt

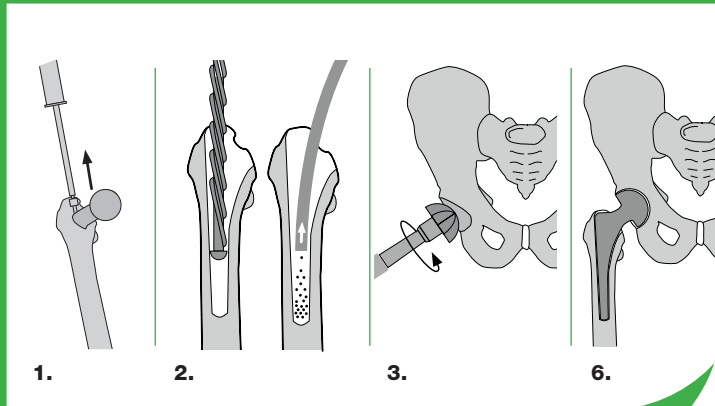
The shiny acetabular head is developed through the bone cement pressurization into the molds and ensures a smooth contact surface between the spacer and the Acetabular cavity.

Through a much porous area, the elution of the antibiotic present in the cement is improved.



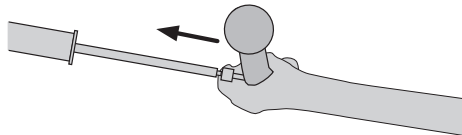
## OPERATING TECHNIQUE

1. Remove the infected prosthesis.
2. Completely debride the prosthesis site and remove every trace of the bone cement used to set the previous implant.
3. Bore the acetabular cavity to achieve the desired cavity.
4. Select and prepare the spacer with the shape suited to the patient's needs.
5. Insert the spacer stem inside the diaphyseal femur canal.  
NOTE: The press-fit design of SpaceFlex Hip and the correct choice of spacer shape ensure the implant will not require further cement.  
Spacer cementing remains at the surgeon's complete discretion.
6. Outcome.

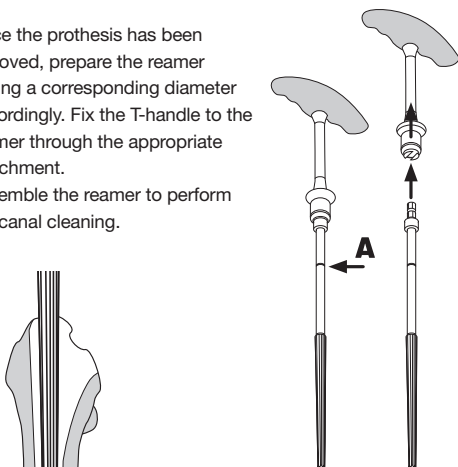


Eventually, use the Trials system as described below:

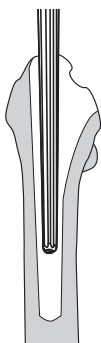
- 1 Explant the infected prosthesis.



- 2 Once the prosthesis has been removed, prepare the reamer having a corresponding diameter accordingly. Fix the T-handle to the reamer through the appropriate attachment. Assemble the reamer to perform the canal cleaning.

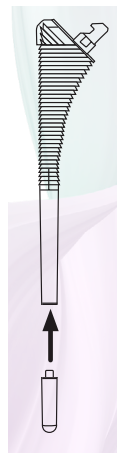


- 3 Clean the femoral canal in order not to exceed the depth indicated by the notch on the reamer (A).

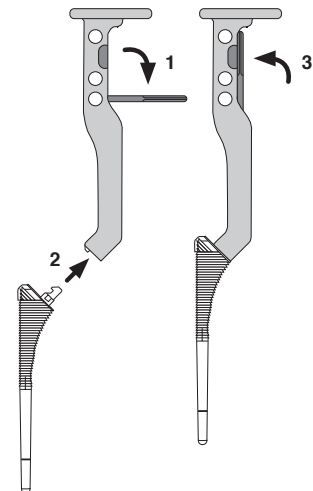


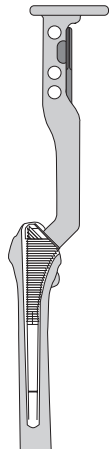
- 4 Based on both the diameter of the reamer used and patient's anatomy, prepare the Broach component provided in the toolbox

- 4.1 Choose the basic component (broach diam. 10mm, 13mm, or 15mm) and, if necessary, screw one of the two corresponding extensions with the distal part to increase the length of the stem.

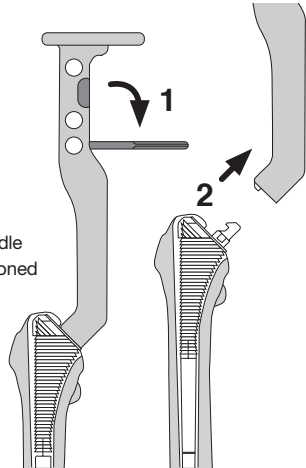


- 4.2 Connect the Broach handle to the assembled broach by using the hook system located in the proximal part of the latter

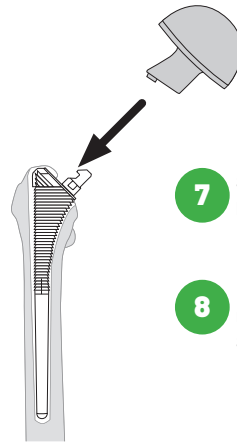




**5** Ensure that the femoral canal is properly prepared to house the assembled broach component and check that every part has been correctly placed.



**6** Disconnect the Broach handle and leave the broach positioned in the femur.



**7** Select the appropriate femoral head and connect it with the broach.

**8** Remove the positioned components and realize the relative spacer with SpaceFlex Hip.



# SPACEFLEX KNEE - MODULARITY

HANDY and EASY disposable custom modular spacer mold directly made in the OR within max 15 minutes [2]. Up to 9 available configurations of spacer realizable in the OR:

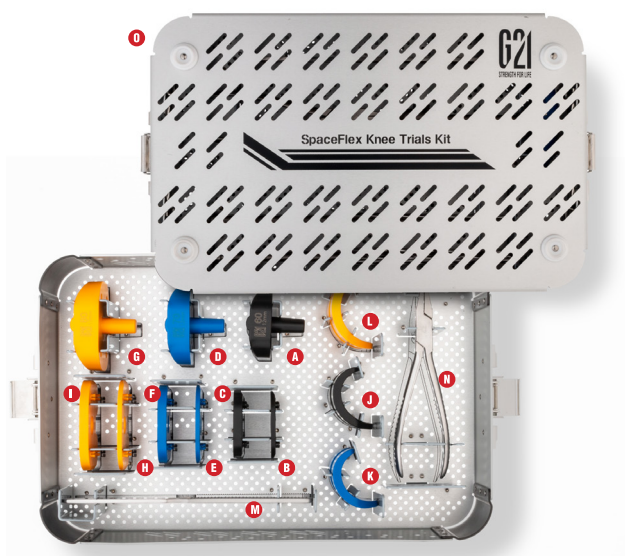
**3 M/L DISTANCES: (60, 70 AND 80) X 3 TIBIAL PLATE HEIGHT (12, 16 AND 20 MM)**

Femoral component, divided by M/L Distance 60mm, 70mm and 80mm



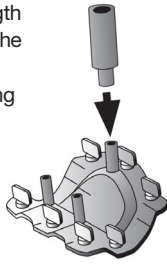
Corresponding Tibial Components molds (M/L 60mm, 70mm and 80mm), composed by a bottom component and 3 molds for the customization of the tibial plate height (12mm, 16mm, 20mm)

A set of trials is available, to offer the surgeon the possibility to prepare the patient's anatomical site and realize the most suitable spacer dimension:

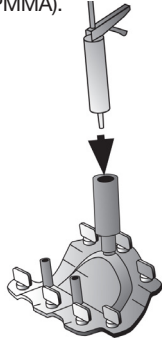


Identification letter	Description	Q.TY
A	SpaceFlex Knee Stemmed Tibial Trial 60mm	1
B	SpaceFlex Knee Tibial Trial 60mm Wedge 16mm	1
C	SpaceFlex Knee Tibial Trial 60mm Wedge 20mm	1
D	SpaceFlex Knee Stemmed Tibial Trial 70mm	1
E	SpaceFlex Knee Tibial Trial 70mm Wedge 16mm	1
F	SpaceFlex Knee Tibial Trial 70mm Wedge 20mm	1
G	SpaceFlex Knee Stemmed Tibial Trial 80mm	1
H	SpaceFlex Knee Tibial Trial 80mm Wedge 16mm	1
I	SpaceFlex Knee Tibial Trial 80mm Wedge 20mm	1
J	SpaceFlex Knee femoral trial 60mm	1
K	SpaceFlex Knee femoral trial 70mm	1
L	SpaceFlex Knee femoral trial 80mm	1
M	Rasp	1
N	Plier	1
O	SpaceFlex Knee Trial Tray	1

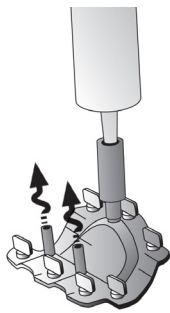
- 1** Insert the cone for injecting bone cement into the appropriate channel, located in the trochlear part of the mold. The coupling must be performed with enough strength to guarantee the components' stability, sealing and integrity.



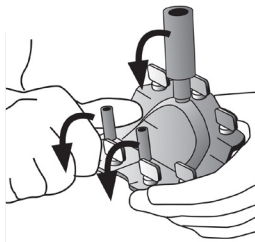
- 2** Insert the cannula of the bone cement injection gun into the injection cone to inject the bone cement (PMMA).



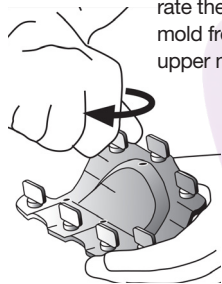
- 3** Slowly and steadily inject the bone cement until it comes out of the condylar venting channels. Immediately clean the leaked cement from the top of the venting channels. Remove the cannula from the supply cone, making sure that the supply cone is full of cement after removal.



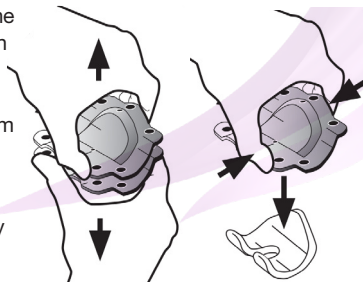
- 4** Once the bone cement has polymerized, bend the venting channels and the injection channel until they break off so that the spacer can be extracted easier.



- 5** Break the 8 sealing clips by rotating them with the fingers and, using a spatula inserted into the appropriate spaces separate the lower mold from the upper mold.



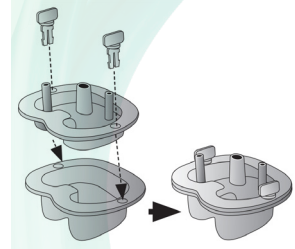
- 6** Taking advantage of the mold's malleability with respect to the bone cement, manually remove the spacer from the upper mold.



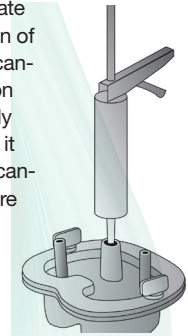
- 7** Refine the spacer's contours, removing any excess residue.

Choose the size of the upper mold (H12/16/20), based on measurements taken from the explanted parts.

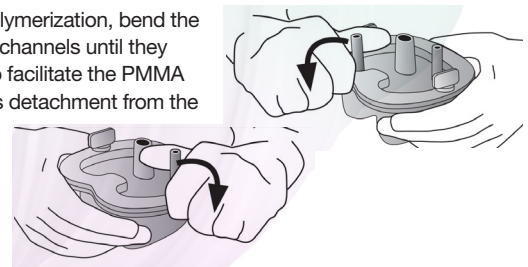
- 1** Insert the selected upper mold into the lower mold and secure it by inserting the sealing clips; once the mold is closed with the clips, it cannot be opened until the cement has hardened. The coupling must guarantee sealing.



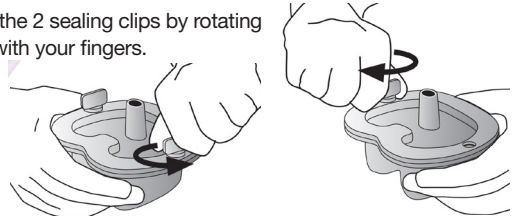
- 2** Once the bone cement is mixed, wait the indicated waiting time before injecting it so that the cement is at the appropriate viscosity to correctly create the device, in order to avoid the formation of PMMA shrinkage or bubbles. Insert the cannula of the bone cement (PMMA) injection gun into the injection channel, then slowly and steadily inject the bone cement until it exits the venting channels. Remove the cannula from the supply channel, making sure that it is full of cement after removal. Immediately clean the leaked cement from the top of the venting channels and the injection channel.



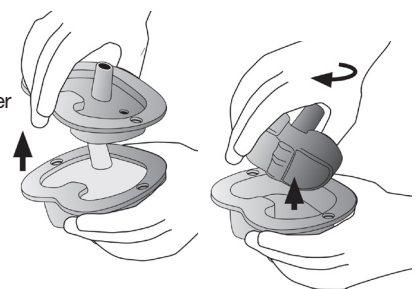
- 3** After polymerization, bend the venting channels until they break to facilitate the PMMA spacer's detachment from the mold.



- 4** Break the 2 sealing clips by rotating them with your fingers.

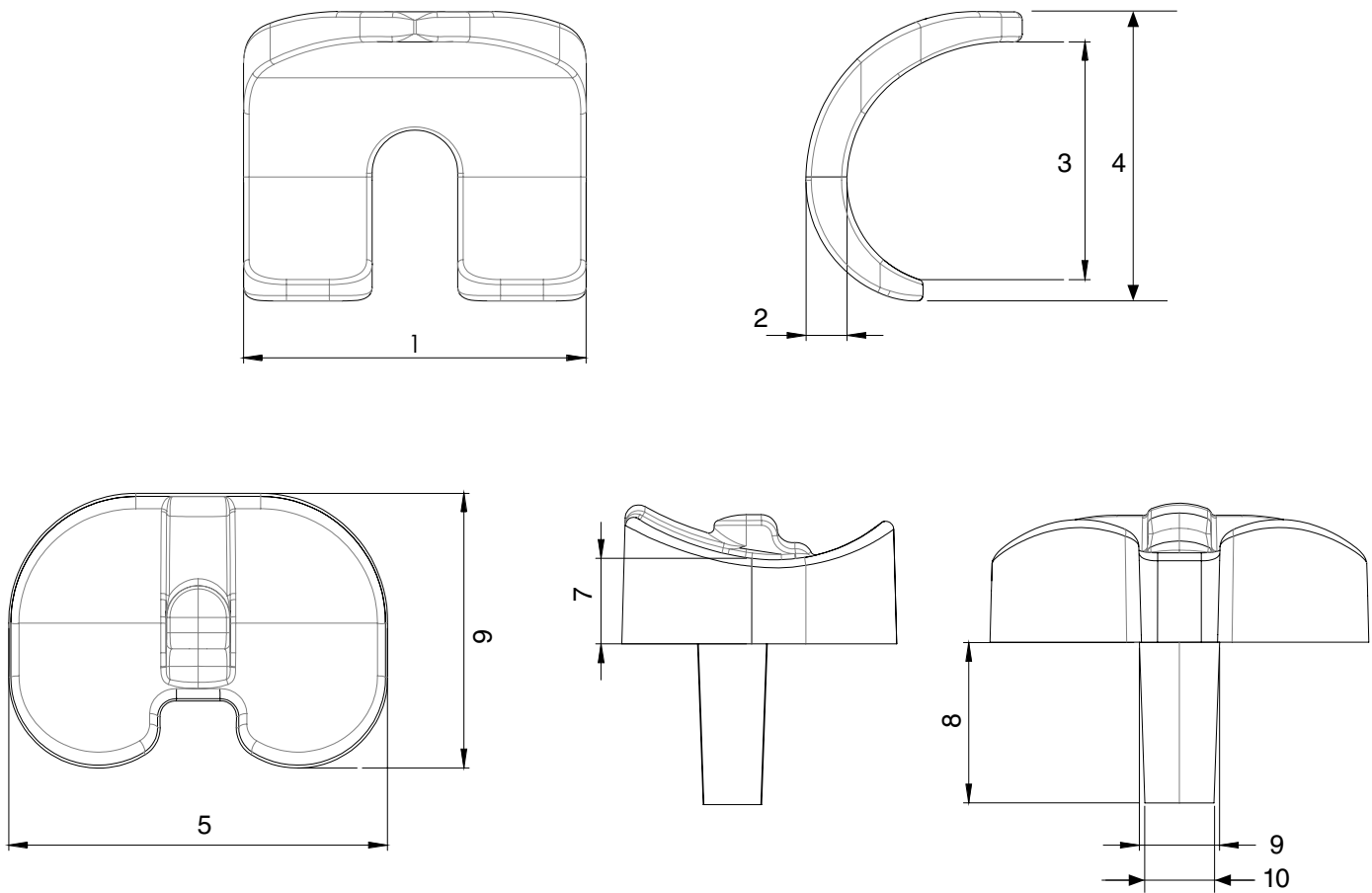


- 5** Using a spatula inserted into the appropriate spaces, separate the lower mold from the upper one. Extract the device by gently twisting it with the hands to help detach it. Refine the spacer's contours, removing any excess residue.



# SPACEFLEX

# KNEE - DIMENSIONS



MM

Description	1	2	3	4	5	6	7	8	9	10
SpaceFlex Knee - 60 mm	54	7.8	44.3	54.3	60.4	44.0	11.7	30	15	13
							19.7			
SpaceFlex Knee - 70 mm	64	7.8	45	54.3	70.4	51.0	11.7	30	15	13
							19.7			
SpaceFlex Knee - 80 mm	74	8.3	52.2	62.7	80.4	59.0	11.7	30	15	13
							19.7			



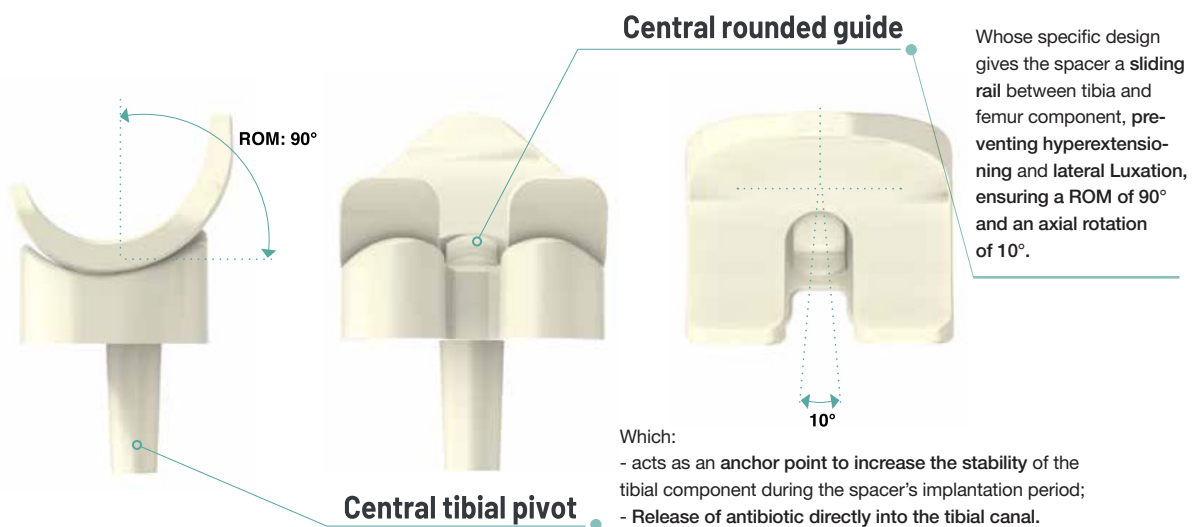
# SPACEFLEX

# KNEE - THE SPACER

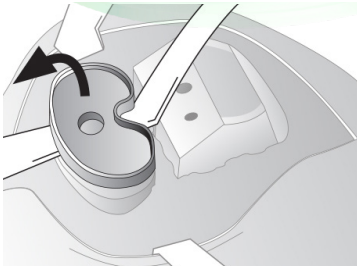


The combination between G21 bone cement and SpaceFlex Knee mold ensures a smooth contact surface [2] that allows it to resist up to 500'000 cycles without breakage and minimizes friction during articulation and helps the patients in maintaining the natural range of motion (ROM) [2, 4, 10].

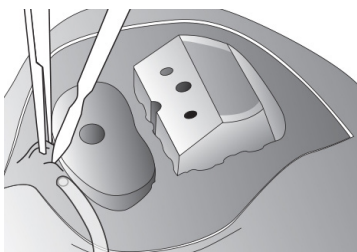
The risk factors for dislocation and instability of knee cement spacers relate to both bone and soft tissue defects encountered at the time of removal of the infected total knee arthroplasty. These complications include knee instability, spacer extrusion, and anterior soft tissue impingement of the antibiotic impregnated cement spacers [5]. Patented anti-dislocation design is granted by:



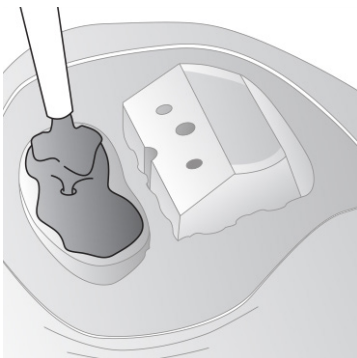
## OPERATING TECHNIQUE



- 1** Completely remove the infected knee prosthesis and any residual bone cement.

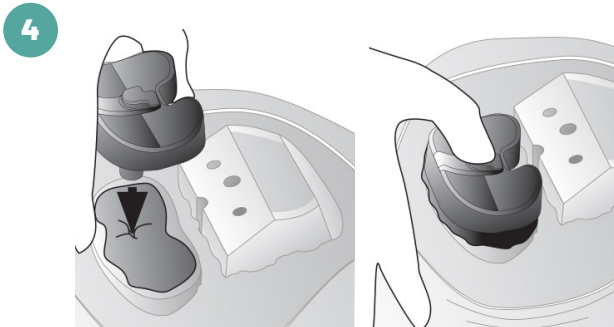


- 2** Perform a complete debridement of the joint space.\*



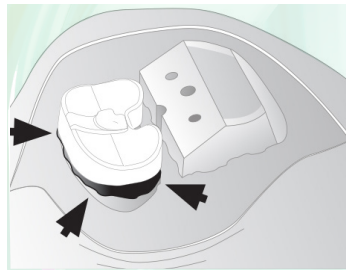
- 3** Put bone cement on the distal posterior surface of the tibial part of the spacer and on the proximal surface of the tibia.

Position the tibial part of the spacer in the bone cement on the proximal surface of the tibia.

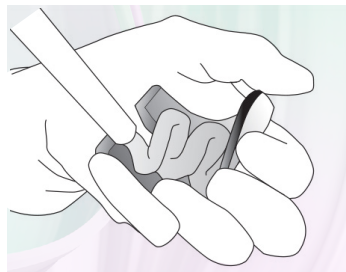


**4**

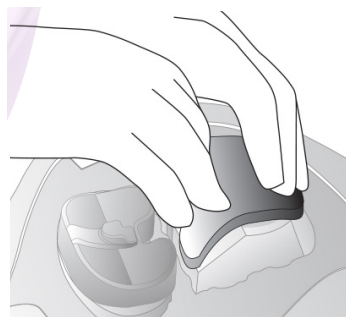
- 5** Thoroughly remove the residual bone cement.



- 6** In order to position the femoral part of the spacer, put bone cement on the posterior face of the spacer.

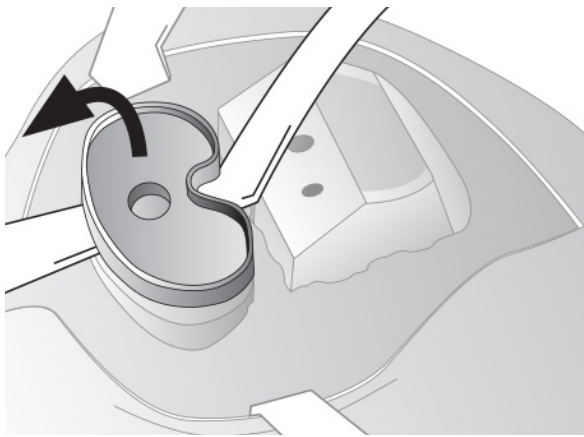


- 7** Carefully position the femoral part of the spacer onto the distal surface of the femur and hold it in place the bone cement has polymerized. Thoroughly clean off any excess bone cement.



\*Eventually, use the Trials system as described below:

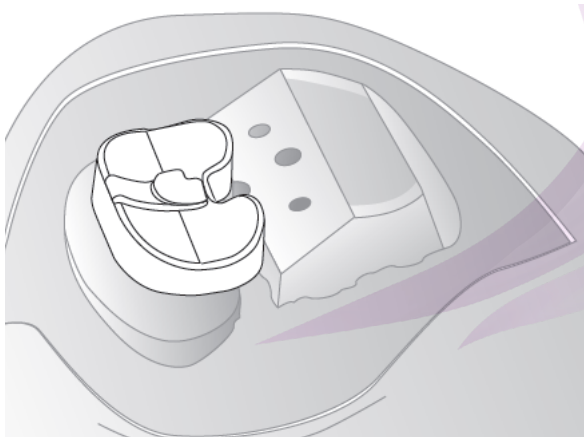
- 1** Explant the infected prosthesis.



- 2** Control the dimension of the infected prosthesis.

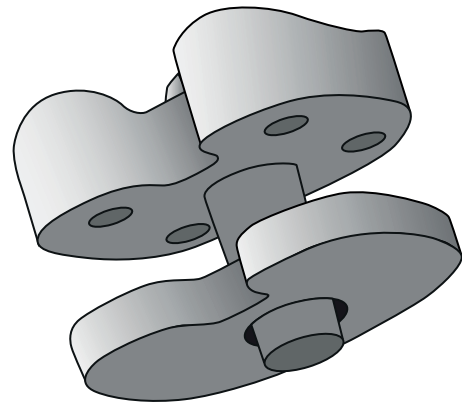
- 3** Extract the selected tibial component from the container, based on its M/L distance

- 4** Place the item in a way to ensure that the tibial canal is deep enough to house the maximum length of the central tibial pivot (30mm).



- 5** Remove the component and - if needed - add one of the two wedges provided (16mm or 20mm) to verify the height of the tibial plate of the spacer.

Note: during the verification phase, consider the thickness of cement that will be used to fix the femoral component to obtain the final spacer.



- 6** Select the corresponding femoral component based on the M/L distance of the tibial component chosen.

- 7** Apply the femoral component to the implant site and check if everything has been properly placed.  
Note: during the verification phase, consider the thickness of cement that will be used to fix the femoral component to obtain the final spacer.



- 8** Remove the positioned components and realize the related spacer with SpaceFlex Knee.



# SPACEFLEX

# SHOULDER - MODULARITY

HANDY and EASY customization between disposable molds and reusable Instrument Kit conceived to obtain a Monoblock Spacer, with a single bone cement injection phase [2].

Up to 46 modular configurations of spacer realizable in the OR:

**4 STEM DIAMETERS X 2 HEADS DIAMETER WITH FIXED OFF SET X 9 STEM LENGTHS**



Disposable mold for Spacer realization:

6 molds could be provided, divided by

the Stem - Head - Offset combination:

- Stem Ø: 8mm - Head - Offset: 42-15

- Stem Ø: 10mm - Head - Offset: 42-15

- Stem Ø: 10mm - Head - Offset: 48-18

- Stem Ø: 12mm - Head - Offset: 42-15

- Stem Ø: 12mm - Head - Offset: 48-18

- Stem Ø: 14mm - Head - Offset: 48-18

SpaceFlex Shoulder instrument kit:

External frame and 6 different,

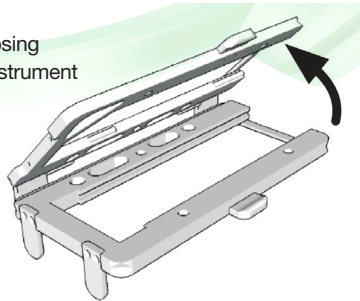
interchangeable, inserts

(one for each mold dimension)

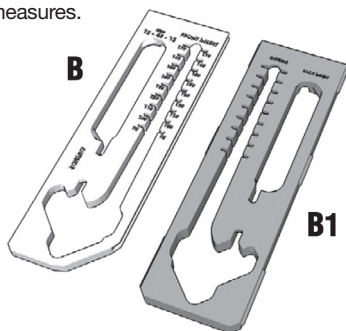
Reusable molds for humeral head realization, provided in the instrument kit, 42 and 48mm.



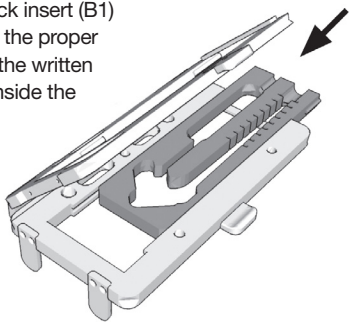
- 1** Unscrew the closing screws of the instrument kit (A)



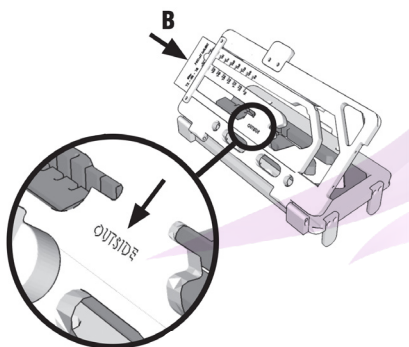
- 2** Select the couple of required inserts (B and B1) according to the desired measures.



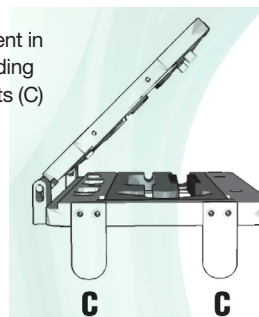
- 3** Take the back insert (B1) and put it in the proper slot so that the written "Inside" is inside the instrument.



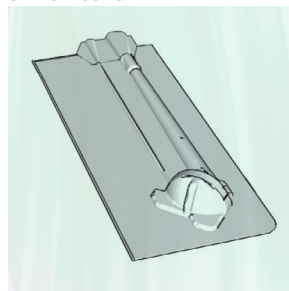
- 4** Take the front insert (B) and put it in the proper slot so that the written "Outside" can be seen outside the instrument.



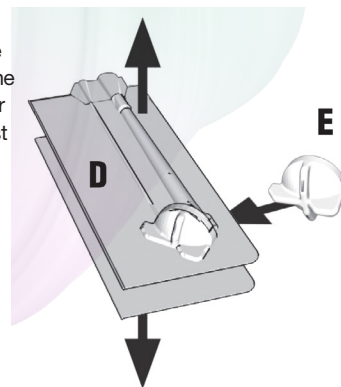
- 5** Place the open instrument in horizontal position standing on the provided supports (C)



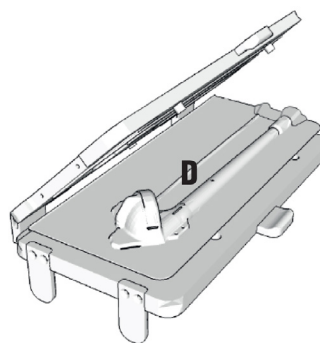
- 6** Take the mold for the preparation of the spacer having the same size of the inserts.



- 7** Open the mold and place inside the head (E) with the appropriate dimension for the space. The head must be placed in the correct spot.



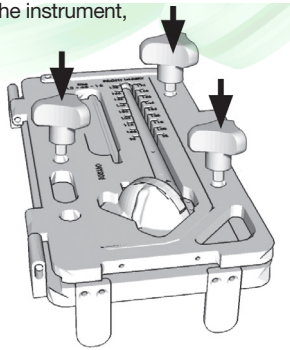
- 8** Place the mold (D) with the head (E) inside the instrument, in the proper spot.



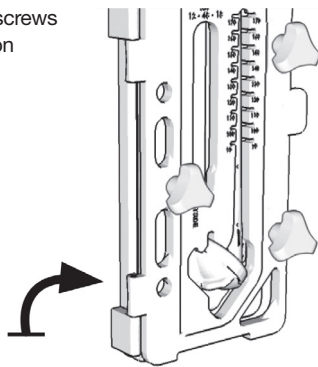
# SPACEFLEX

# SHOULDER SPACER REALIZATION

- 9** After inserting the mold in the instrument, close the closing screws, making sure that cement injecting point and outgoing air hole are in the right position.

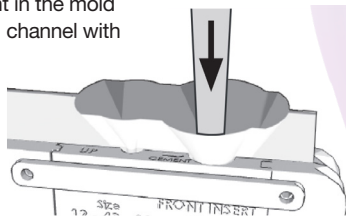


- 10** Close the closing screws (A) in stable position



- 11** Prepare the bone cement to inject in the mold (according to the bone cement IFUs)

- 12** Inject the bone cement in the mold through the dedicated channel with the proper mixing and delivery system

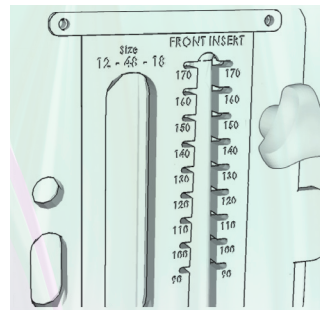


SpaceFlex Shoulder Cod. 900001 xx yy zz			
xx : Ø stem (mm)	yy: Ø head (mm)	zz: head offset (mm)	Recommended G3/G3A bone cement units #No.
8	42	15	2 x 40 gr
10	42	15	2 x 40 gr
10	48	18	2 x 40 gr
12	42	15	2 x 40 gr
12	48	18	2 x 40 gr
14	48	18	2 x 40 gr

Warning: the amounts given above were measured considering the use of G3/G3A bone cement and the PicoMix Syringe mixing device - note that the volume of other bone cements may change the amount of bone cement to use to correctly fill the SpaceFlex Shoulder molds.

NOTE: inject the bone cement slowly and constantly to minimize formation of air bubbles, the leakage or deformation of the spacer.

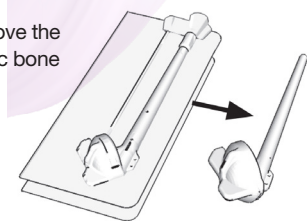
- 13** Check the total desired length of the spacer by verifying the numbers on the front of the instrument.



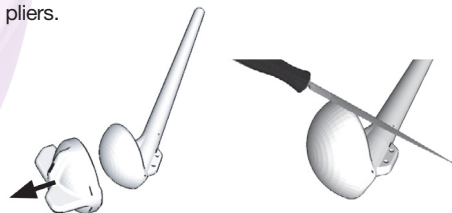
- 14** Wait for the complete polymerization of the bone cement.

- 15** Once the cement polymerized, unscrew the closing screws of the instrument and extract the mold containing the spacer.

- 16** Open the mold and remove the spacer made of antibiotic bone cement.

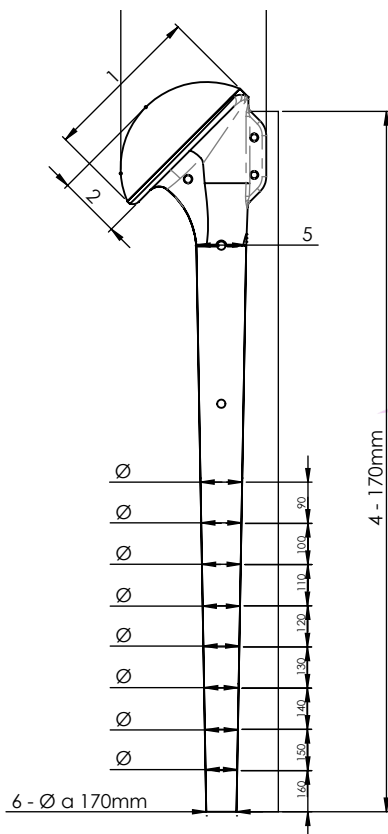


- 17** Remove the head from the burrs with sterile gloves or pliers.



- 18** If necessary, remove the flashes with sterile rasps, then the spacer is ready to be implanted.





Description	Stem Length	3						
		1	2	42-15	48-18	4	5	6
Head 42-15	/	38,1	14,5	/				
Head 48-18	/	44,1	17,5					
Stem 8mm	90			34,9	/	89,3	8	6,8
Stem 10mm	90			89,3	10	8,5		
	100			98,9		8,4		
	110			109,3		8,2		
	120			119,9		8,0		
	130			129,7		7,9		
	140			140		7,6		
	150			149,7		7,5		
160	160	7,4						
Stem 12mm	170	169,8	7,3					
	90	89,3	12	9,6				
	100	98,9		9,2				
	110	109,3		8,9				
	120	119,9		8,5				
	130	129,7		8,2				
	140	140		7,8				
150	149,7	7,5						
Stem 14mm	160	160	7,3					
	170	169,8	7,1					
	90	89,3	14	11,7				
	100	98,9		11,4				
	110	109,3		11,0				
	120	119,9		10,7				
	130	129,7		10,4				
140	140	10,1						
150	149,7	9,8						
160	160	9,5						
170	169,8	9,2						

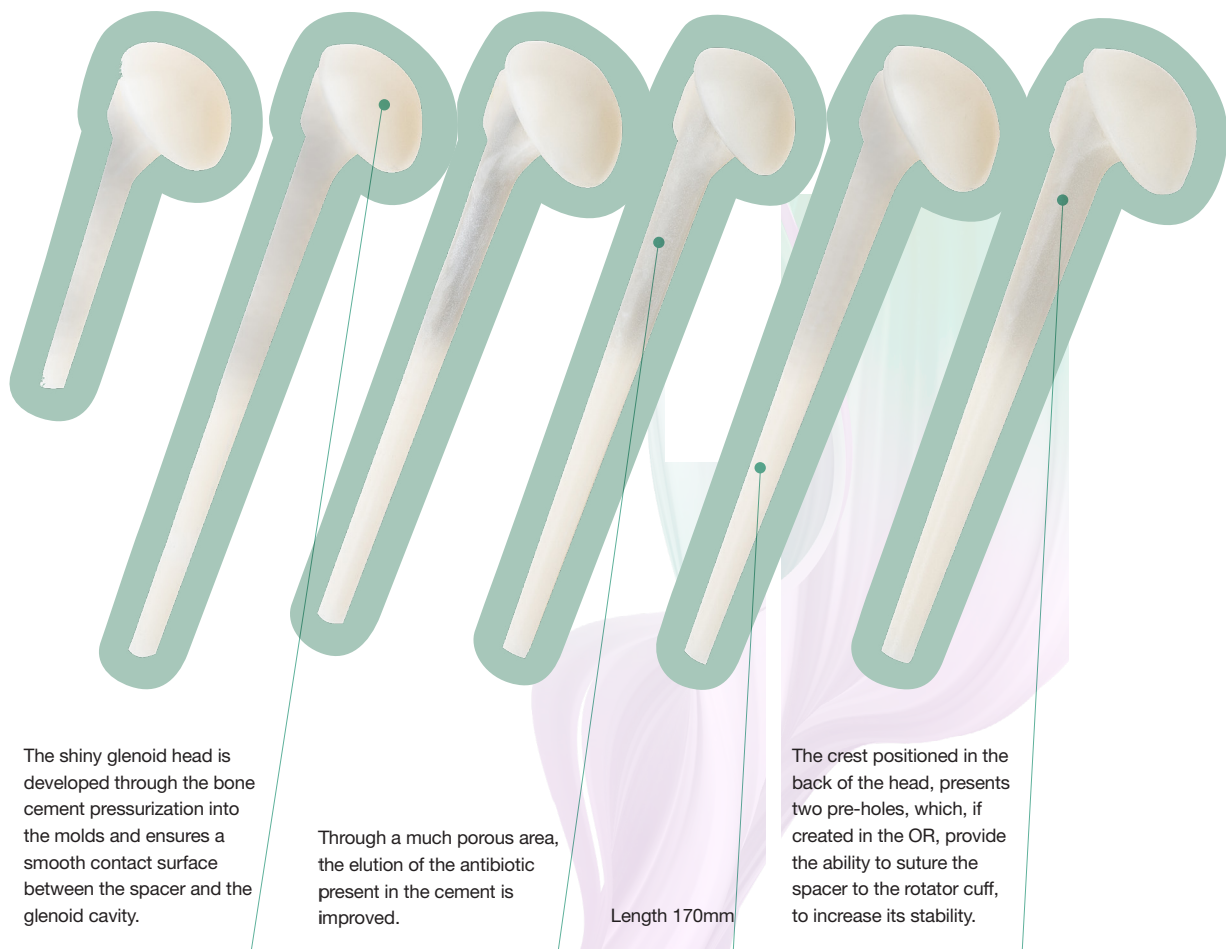
# SPACEFLEX

# SHOULDER - THE SPACER

The combination between G21 bone cement and SpaceFlex Shoulder mold ensures a smooth contact surface between the humeral head and glenoid cavity which minimizes the friction during motion [2].

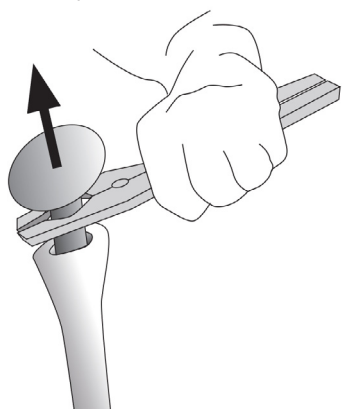
Humeral head and stem design enhance safety mobility, allowing an anatomical press fitting and persevering the tensioning of the soft tissue [6, 7, 8, 9].

The material and design of metal core reinforcement guarantees a high level of safety in resistance of the spacer [7].

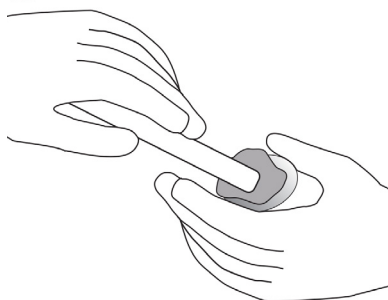


## OPERATING TECHNIQUE

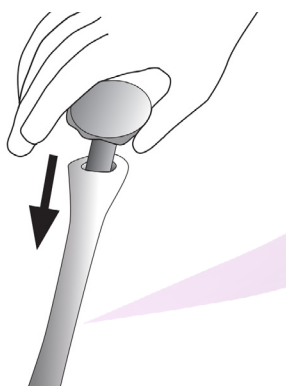
- 1** Remove the prosthesis and clean the host site by aggressive debridement, removing all residues of cement, if present.



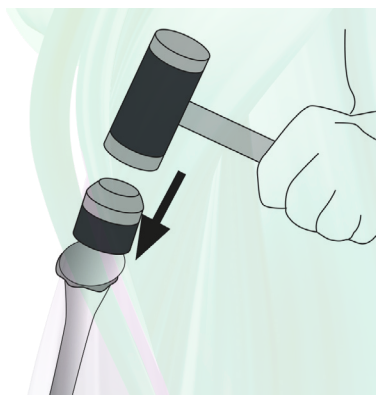
- 2** Apply antibiotic loaded bone cement to underside of spacer head.



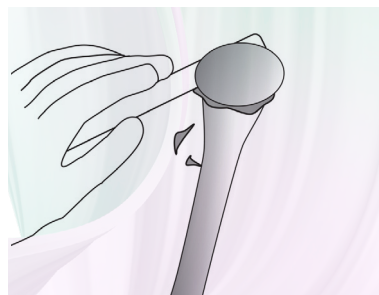
- 3** Insert the shoulder spacer into the humeral canal while approximating anatomical version.



- 4** When further seating is desired, use a head-pusher for leverage. Do not impact the shoulder spacer with a mallet directly.



- 4** Remove all extruding bone cement with a curette and reduce the shoulder.





PRODUCT	DESCRIPTION	CONTENT	REF.
SpaceFlex Hip 10	Custom modular Hip mold spacer	<ul style="list-style-type: none"> <li>· 2 stem 10 molds, coupled</li> <li>· 4 femoral head molds (48, 52, 56, 60)</li> <li>· 1 titanium core reinforcement (pre-fixed into the coupled stem molds by 2 PMMA centering pins)</li> <li>· 2 titanium core reinforcement extensions 40 and 80mm</li> <li>· 1 closing cup for the injection point</li> </ul>	900005 10
SpaceFlex Hip 13	Custom modular Hip mold spacer	<ul style="list-style-type: none"> <li>· 2 stem 13 molds, coupled</li> <li>· 4 femoral head molds (48, 52, 56, 60)</li> <li>· 1 titanium core reinforcement (pre-fixed into the coupled stem molds by 2 PMMA centering pins)</li> <li>· 2 titanium core reinforcement extensions 40 and 80mm</li> <li>· 1 closing cup for the injection point</li> </ul>	900005 13
SpaceFlex Hip 15	Custom modular Hip mold spacer	<ul style="list-style-type: none"> <li>· 2 stem 15 molds, coupled</li> <li>· 4 femoral head molds (48, 52, 56, 60)</li> <li>· 1 titanium core reinforcement (pre-fixed into the coupled stem molds by 2 PMMA centering pins)</li> <li>· 2 titanium core reinforcement extensions 40 and 80mm</li> <li>· 1 closing cup for the injection point</li> </ul>	900005 15
SpaceFlex Hip Instrument Kit	Instrument for the housing of the hip molds	<ul style="list-style-type: none"> <li>· 1 inferior part (with its standing supports) (Ref. 600642)</li> <li>· 1 superior part (Ref. 600643)</li> <li>· Femoral head mold holder (Ref. 600644)</li> <li>· 1 Locking screw "A" (Ref. 600645)</li> <li>· 2 Locking screws "B" (Ref. 600646)</li> <li>· 3 locking screw "C" (Ref. 600647)</li> </ul>	900008
SpaceFlex Hip Trial	Instrument for choosing the correct mold size	<ul style="list-style-type: none"> <li>· SpaceFlex Hip Trial Broach 10/13/15 mm</li> <li>· SpaceFlex Hip Trial Head 48/52/56/60 mm</li> <li>· SpaceFlex Hip Broach Extension S (10/13/15 mm)</li> <li>· SpaceFlex Hip Broach Extension L (10/13/15 mm)</li> <li>· Conical Reamer 10/13/15 mm</li> <li>· T-Handle</li> <li>· Broach Handle</li> <li>· Plier</li> <li>· Rasp</li> <li>· SpaceFlex Hip Trial Tray</li> </ul>	900202

PRODUCT	DESCRIPTION	CONTENT	REF.
SpaceFlex Knee 60	Custom modular knee mold spacer	<ul style="list-style-type: none"> <li>· 1 Femoral Mold M/L 60 mm</li> <li>· 1 lower tibial mold M/L 60 mm</li> <li>· 3 lower tibial mold covers H12, H16, H20</li> <li>· 1 injector</li> <li>· 2 clips</li> </ul>	900189 60
SpaceFlex Knee 70	Custom modular knee mold spacer	<ul style="list-style-type: none"> <li>· 1 Femoral Mold M/L 70 mm</li> <li>· 1 lower tibial mold M/L 70 mm</li> <li>· 3 lower tibial mold covers H12, H16, H20</li> <li>· 1 injector</li> <li>· 2 clips</li> </ul>	900189 70
SpaceFlex Knee 80	Custom modular knee mold spacer	<ul style="list-style-type: none"> <li>· 1 Femoral Mold M/L 80 mm</li> <li>· 1 lower tibial mold M/L 80 mm</li> <li>· 3 lower tibial mold covers H12, H16, H20</li> <li>· 1 injector</li> <li>· 2 clips</li> </ul>	900189 80
SpaceFlex Knee Trial	Instrument for choosing the correct mold size	<ul style="list-style-type: none"> <li>· SpaceFlex Knee Stemmed Tibial Trial 60/70/80 mm</li> <li>· SpaceFlex Knee Tibial Trial 60/70/80 mm Wedge 16 mm</li> <li>· SpaceFlex Knee Tibial Trial 60/70/80 mm Wedge 20 mm</li> <li>· SpaceFlex Knee femoral trial 60/70/80 mm</li> <li>· Rasp</li> <li>· Plier</li> <li>· SpaceFlex Knee Trial Tray</li> </ul>	900201

PRODUCT	DESCRIPTION	CONTENT	REF.
SpaceFlex Shoulder 8 42 15	Custom modular Shoulder mold spacer	<ul style="list-style-type: none"> <li>· 1 spacer mold with 8 mm steam diameter, 42 mm head diameter and 15 mm head offset.</li> <li>· 1 AISI 316 L core reinforcement (pre-fixed into the spacer by 2 PMMA centering pins)</li> </ul>	900001 8 42 15
SpaceFlex Shoulder 10 42 15	Custom modular Shoulder mold spacer	<ul style="list-style-type: none"> <li>· 1 spacer mold with 10 mm steam diameter, 42 mm head diameter and 15 mm head offset.</li> <li>· 1 AISI 316 L core reinforcement (pre-fixed into the spacer by 2 PMMA centering pins)</li> </ul>	900001 10 42 15
SpaceFlex Shoulder 10 48 18	Custom modular Shoulder mold spacer	<ul style="list-style-type: none"> <li>· 1 spacer mold with 10 mm steam diameter, 48 mm head diameter and 18 mm head offset.</li> <li>· 1 AISI 316 L core reinforcement (pre-fixed into the spacer by 2 PMMA centering pins)</li> </ul>	900001 10 48 18
SpaceFlex Shoulder 12 42 15	Custom modular Shoulder mold spacer	<ul style="list-style-type: none"> <li>· 1 spacer mold with 12 mm steam diameter, 42 mm head diameter and 15 mm head offset.</li> <li>· 1 AISI 316 L core reinforcement (pre-fixed into the spacer by 2 PMMA centering pins)</li> </ul>	900001 12 42 15
SpaceFlex Shoulder 12 48 18	Custom modular Shoulder mold spacer	<ul style="list-style-type: none"> <li>· 1 spacer mold with 12 mm steam diameter, 42 mm head diameter and 15 mm head offset.</li> <li>· 1 AISI 316 L core reinforcement (pre-fixed into the spacer by 2 PMMA centering pins)</li> </ul>	900001 12 48 18
SpaceFlex Shoulder 14 48 18	Custom modular Shoulder mold spacer	<ul style="list-style-type: none"> <li>· 1 spacer mold with 14 mm steam diameter, 48 mm head diameter and 18 mm head offset.</li> <li>· 1 AISI 316 L core reinforcement (pre-fixed into the spacer by 2 PMMA centering pins)</li> </ul>	900001 14 48 18
SpaceFlex Shoulder Instrument Kit	Instrument for the housing of the shoulder molds	<ul style="list-style-type: none"> <li>· 1 instrument kit (Ref. 600649)</li> <li>· 6 inserts (Ref. 600123 0842/1042/1048/1242/1248/1448)</li> <li>· 2 humeral head molds (42, 48) (Ref. 600119, 600120)</li> </ul>	900012

[1] Mechanical and elution properties of G3 Low Viscosity bone cement loaded up to three antibiotics, *G. Cacciola, F. De Meo, P. Cavaliere, Journal of Orthopaedics 15 (2018) 1004–1007.*

[2] Data on file of G21 S.r.l.

[3] ISO 7206-4:2010 “Implant for surgery – Partial and total hip joint prostheses – Part 4: Determination of endurance properties and performance”

[4] Recovery of knee mobility after a static or mobile spacer in total knee infection, *J. Brunnekreef, G. Hannink, M. de Waal Malefijt, Acta Orthopædica Belgica, Vol. 79 - 1 - 2013.*

[5] Antibiotic Cement Spacers in Total Hip and Total Knee Arthroplasty: Problems, Pitfalls, and Avoiding Complications, *R.S.J. Burnett, J.C. Clohisy, R.L. Barrack, Infection and Local Treatment in Orthopedic Surgery pp 92-111.*

[6] Use of a Functional Antibiotic Spacer in Treating Infected Shoulder Arthroplasty, *J. C. Levy, J. Triplet, N. Everding, Orthopedics. 2015; 38(6):e512-e519.*

[7] Antibiotic Spacers in Shoulder Arthroplasty: Comparison of Stemmed and Stemless Implants, *E. M. Padegimas, A. Narzikul, C. Lawrence, Be. A. Hendy, J. A. Abboud, M. L. Ramsey, G. R. Williams, S. Namdari, Clinics in Orthopedic Surgery 2017;9:489-496.*

[8] Definitive Treatment of Infected Shoulder Arthroplasty With a Cement Spacer, *S. A. Mahure, B. Mollon, S. Yu, Y. W. KWon, J. D. Zuckerman, Orthopedics. 2016 Sep 1;39(5):e924-30.*

[9] Antibiotic-loaded bone cement reduces deep infection rates for primary reverse total shoulder arthroplasty: a retrospective, cohort study of 501 shoulders, *R. J. Nowinski, R. J. Gillespie, Y. Shishani, B. Cohen, G. Walch, R. Gobezie, J Shoulder Elbow Surg (2012) 21, 324-328*

[10] Preliminary results of the tribological performance of new modular temporary knee spacer antibiotic-impregnated, *S. Affatato, F. Foroni, M. Merola, F. Baldacci, Journal of the Mechanical Behavior of Biomedical Materials 95 (2019) 205-209.*