fuse

STERIZO™

PRIMARY KNEE SYSTEM

Surgical Technique

TABLE OF CONTENTS

STERIZO Total Knee System

Stability

Choose your constraint style — Cruciate Retained, Ultra Congruent/Anterior Stabilized, Posterior Stabilized, or Posterior Stabilized Plus/Semi Constrained, the STERIZO Total Knee System provides stability for your patients throughout the entire range of motion.

Strength

STERIZO literally means strong. The STERIZO Total Knee System is made in America, bringing you strength in confidence, quality, and longevity, as well as clinical outcomes and patient satisfaction.

Simplicity

The STERIZO Total Knee System was designed with efficiencies in mind. Both in elegant implants designed to accommodate a wide range of patient anatomies, and streamlined modular instrumentation to assist you with simplifying the surgical procedure and improving Operating Room efficiencies.

High Flex Design

The STERIZO Total Knee System was engineered to deliver high flexion across all constraint platforms. 139° of flexion allows your patients to achieve strong, reproducible results, all while maintaining anatomic high-flex mobility.

STERIZO Total Knee System

1. Indications for Use:

The STERIZO Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is designed for cemented use only.

2. Pre-Operative Planning:

Obtain both A-P and lateral standing radiographs. This surgical technique is for guidance on the use of the STERIZO Total Knee System Instrumentation. Each surgeon must evaluate the suitability of the techniques based on his or her medical training and experience.

3. Femoral Preparation:

Utilize the starting **Femoral IM Drill** to enter the femoral canal (Figure 1). Entry point should be roughly 2-5mm anterior to the femoral notch.

Figure 1

3.1 Femoral IM Alignment:

Set the **Femoral IM Alignment Guide** at the predetermined Valgus Angle between 1-9 degrees. Be sure to note Left or Right.

Insert the **Intramedullary (IM) Rod** into the Femoral IM Alignment Guide. Connect the **Distal Femoral Alignment Guide** to the Femoral IM Alignment Guide then connect the **Distal Femoral Cutting Guide**. Place the assembly into the femoral IM canal ensuring the guide is contacting the distal femur. (Figure 2).

Figure 2

1. Femoral IM Drill
   M-3120-5000

2. Femoral IM Alignment Guide M-3120-5002

3. Intramedullary (IM) Rod
   M-3120-5001

4. Distal Femoral Alignment Guide
   M-3120-5005

5. Distal Femoral Cutting Guide
   M-3120-5006

3.2 Distal Femoral Cut:

Using **Smooth Pins** and the **Pin Driver**, pin the Distal Femoral Cutting Guide in place at the 0-degree holes with two pins and a third pin laterally (Figure 3), ensuring that the Femoral IM Alignment Guide is flush with the distal femur (Figure 3). Remove alignment guides and Intramedullary (IM) Rod.

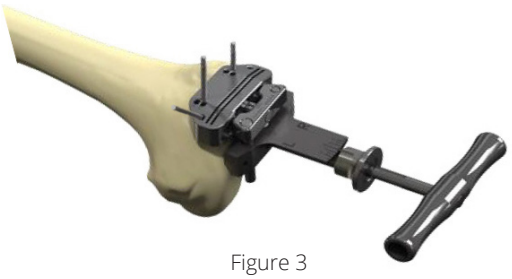


Figure 3

Use a .05in. (1.27mm) Saw Blade for resections.

Resection of 9mm is accomplished through the 0 slot. Adjustment of resection level can be accomplished by: (Figure 4);

1) Additional 3mm of resection by cutting through the -3 slot
2) Distal Femoral Cutting Guide may be moved on pins +/-2mm

Figure 4

After completion of the distal femoral cut, remove cutting block and remove pins with **Pin Extractor** (Figure 5). Leave pins in place if desired to address additional distal femoral resection if needed during gap balancing.

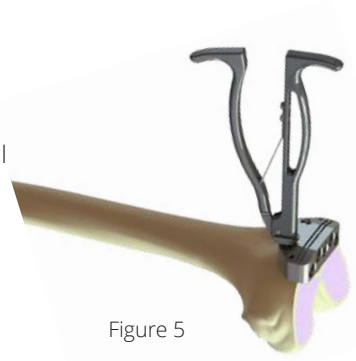


Figure 5

6. Smooth Pin
M-3120-5003

7. Pin Driver
M-3120-5004

8. Pin Extractor
M-3120-5007

3.3 Femoral Component Sizing:

Place the appropriate **Femoral Sizer** (Anterior/Posterior Reference) on the distal femur. Make sure the referencing feet are touching the posterior condyles and are flush with the distal femur. If the posterior condyles are deficient, align the pins with the epicondyles. Place the anterior stylus tip where you want the anterior cut to exit the cortex, which is typically along the anterior medial cortex (Figure 6). Pin the sizer in place by drilling the appropriate holes (Figure 7).

Figure 6

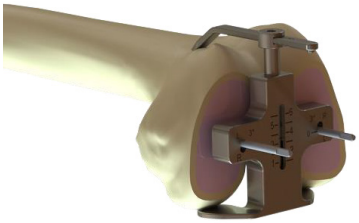


Figure 7

Adjustment of external rotation between 0 and 3 degrees can be accomplished by: (Figure 8);

1. Right Knee: 3 degree external rotation can be established by drilling both holes indicated by R.
2. Left Knee: 3 degree external rotation can be established by drilling both holes indicated by L.
3. Right or Left Knee: 0 degree rotation can be established by drilling into the two bottom holes indicated by 0.

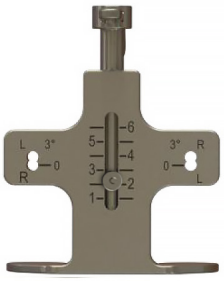


Figure 8

Reference the sizing guide to establish the correct femoral component size (1-6). If using the Anterior Sizer, it is recommended to use the smaller of two sizes if the measurement is between sizes. However, if using the Posterior Sizer, it is recommended to use the larger size. Select the correctly sized Femoral 4 in 1 Cut Guide based on femur sizer measurement.

9. Femoral Sizer
   Anterior/Posterior
   M-3120-5008
   M-3120-5009

3.4 Femoral 4 in 1 Cut Guide:

After establishing the appropriate size, choose the corresponding **Femoral 4 in 1 Cut Guide** and place it in the pre-drilled holes on the distal femur. Impact the block flush onto the distal femur. Check the anterior and posterior cutting slots with the **Blade Gauge** to confirm appropriate bone removal and exit path of the Saw Blade during the anterior cut (Figure 9).

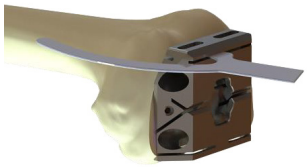


Figure 9

If position adjustment of the femur is desired, the **Repositioning Block** may be used to move the 4 in 1 Cut Guide 1, 2, 3, or 4mm either anteriorly or posteriorly on the femur. To shift the position of the femur, remove the 4 in 1 Cut Guide with the **Slap Hammer** and place the Repositioning Block pins into the same holes in the resected distal femur. With the Smooth Pins, create new holes using the desired millimeters of movement as shown on the face of the Repositioning Block. If the numbers are showing right-side up, then drilling into those holes will move the femur in the anterior direction by the number of millimeters shown. If the numbers are upside down, then using those holes will move the position of the femur posteriorly by that amount. The Repositioning Block may be turned to face in either direction to achieve the exact number of millimeters of shift required (Figure 10).

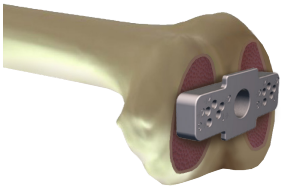


Figure 10

Once confirmed, pin the Femoral 4 in 1 Cut Guide through both medial and lateral pin holes to secure the block (Figure 11). Resect the femur with a 0.5in. (1.27mm) Saw Blade beginning with the anterior cut slot, then moving to the posterior slot, then anterior and posterior chamfers.

Figure 11

3.5 CR Femoral Trial Preparation:

Place the appropriate size **CR Femoral Trial** component onto the lock-on **Femoral Driver**; align and impact onto the femur until the CR Femoral Trial is fully seated (Figure 12). Align the CR Femoral Trial and drill the distal femoral lug holes with the **CR Femoral Lug Drill** (Figure 13).

Figure 12

Figure 13

10. Femoral 4 in 1 Cut Guide
    M-3120-50XX

11. Blade Gauge
    M-3120-5016

12. Repositioning Block
    M-3120-5053

13. CR Femoral Trial
    M-3111-1XXX

14. Femoral Driver
    M-3120-5026

15. CR Femoral Lug Drill
    M-3120-5054

16. Slaphammer
    M-3220-5005

The CR Femoral Trial may be removed with the Slaphammer by inserting the tip of the Slaphammer into the center of the CR Femoral Trial and rotate 90° to engage (Figure 14).

Figure 14

3.6 PS Femoral Preparation:

Place the **PS Notching Jig** onto the resected femur using the **PS Notching Jig Inserter** with the **Modular Handle** attached (Figure 15).

Figure 15

Align the PS Notching Jig and pin into place to provide room for the PS notch. Use the **PS Reamer** to mill out the posterior slot first followed by the anterior slot (Figure 16/17).

Step 1: Posterior

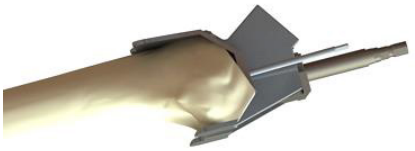


Figure 16

Step 1: Anterior

Figure 17

It is important to ensure appropriate fit of the femoral component. Using the **PS Punch** with the Modular Handle attached, remove the remaining bone fragments. Follow the same posterior first, then anterior slot procedure as performed in the PS Reamer steps (Figure 18/19). Remove the PS Notching Jig by removing the pins with the Pin Extractor.

Step 1: Posterior

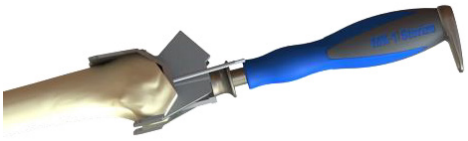


Figure 18

Step 1: Anterior

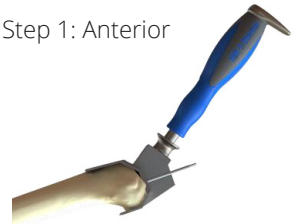


Figure 19

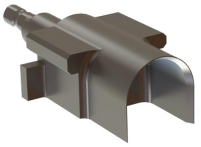
17. PS Notching Jig
M-3120-50XX

18. PS Notching Jig Inserter
M-3120-5051

19. Modular Handle
G910100

20. PS Reamer
M-3120-5023

21. PS Punch
M-3120-5052



3.7 PS Femoral Trial Preparation:

Place the appropriate size **PS Femoral Trial** component onto the lock-on Femoral Driver. Align the PS Femoral Trial onto the femur and impact until the PS Femoral Trial is fully seated (Figure 20).

Figure 20

The PS Femoral Trial may be removed with the Slaphammer by inserting the tip of the Slaphammer into the center of the PS Femoral Trial and rotating 90° to engage (Figure 21).

Figure 21

22. PS Femoral Trial
M-3111-220X

23. Femoral Driver
M-3120-5026

24. Slaphammer
M-3220-5005

4. Tibial Preparation

5° of posterior slope has been incorporated into all styles of tibial inserts. It is at the discretion of the surgeon to increase or decrease posterior slope (Figure 22).

Figure 22

4.1 Extramedullary (EM) Tibial Resection:

Assemble the **Tibial EM Alignment Guide** with the left or right **Tibial Cutting Guide**. With the knee fully flexed, place the ankle clamp over the distal tibia. Proximally, place the Tibial EM Alignment Guide against the tibia. Adjust the guide so that it is parallel to the long axis of the tibia (Figure 23).

4.2 Intramedullary (IM) Tibial Resection:

Assemble the **Tibial IM Guide** with the left or right Tibial Cutting Guide and the Intramedullary (IM) Rod. Insert the Intramedullary (IM) Rod into the tibial canal and allow to pass through the isthmus of the canal (Figure 24). Position the Tibial IM Guide in order to perform a proximal tibial resection.

Using either the EM or IM option, place the **Tibial Stylus** onto the Tibial Cutting Guide. The two options for positioning the Tibial Cutting Guide with the Tibial Stylus are 2mm or 9mm. To position the cutting block so that bone resection will occur 2mm below the stylus tip contact, the 2mm stylus tip must be positioned on the low point of the tibial plateau. To position the cutting block 9mm below, the 9mm stylus tip must be positioned on the high point of the tibial plateau. Pin block into place at the 0-degree holes with two pins (Figure 25) and a third pin laterally for Tibial Cutting Guide stability. Remove Tibial Stylus and Tibial Alignment Guide from pinned Tibial Cutting Guide.

If verification of tibial alignment is desired, attach the **Tibial Alignment Rod Holder** to the Tibial Cutting guide and insert the **Alignment Rod** before resecting the tibia. If alignment is satisfactory, then resect with Saw Blade though the cut slot (Figure 26).

Figure 23

Figure 24

Figure 25

Figure 26

25. Tibial Cutting Guide
    M-3220-5000 (L)
    M-3220-5001 (R)

26. Tibial EM Alignment Guide
    M-3220-5002

27. Tibial IM Guide
    M-3220-5003

28. Tibial Stylus
    M-3220-5004

29. Tibial Alignment Rod holder
    M-3220-5056

Altering the tibial resection thickness with the Tibial Cutting Guide can be accomplished by (Figure 26);

1) Repositioning the block on the pins at +/-2mm.

Figure 26

If satisfied with tibial resection, remove pins with the Pin Extractor, or leave pins in place for flexion and extension gap balancing.

4.3 Balance Flexion and Extension Gaps:

The flexion and extension gaps are confirmed utilizing the appropriate **Gap Gauge Insert**. Start with 9mm base and add shims until flexion and extension are balanced. The extramedullary alignment can be checked in both flexion and extension by inserting the Alignment Rod into the hole of the Gap Gauge (Figure 27).


Figure 27

After removing all peripheral osteophytes and checking the flexion and extension gap, if either gap is unbalanced, the following balancing techniques can be used:

1) Flexion & Extension are too tight - place the Tibial Cutting Guide back on existing pins and resect more bone from the proximal tibia.

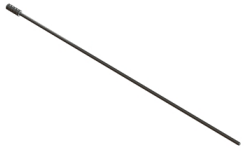
2) Flexion too tight & Extension balanced - downsize the femoral component, which will remove more bone posteriorly and not affect the extension gap.

3) Flexion balanced & Extension too tight - place the Distal Femoral Cutting Guide onto existing pins and remove more bone on the distal femur.

30. Gap Gauge
M-3220-5006

31. Gap Gauge Insert
M-3220-500X

32. Alignment Rod
M-3120-5028



4.4 Tibial Trial Preparation:

The Sterizo™ Knee PS/CR System provides full interchangeability between tibia and femoral sizes.

The Sterizo™ Knee UC System provides one size up or down between the tibia and femoral sizes.

Attach the **Tibial Tray Trial Handle** to the **Tibial Tray Trial** that best covers the proximal tibia (Figure 28). If desired, Tibial Tray Trial alignment and varus/valgus position may be checked by inserting the Alignment Rod into the hole on the Tibial Tray Trial Handle (Figure 29).

Figure 28

Figure 29

Once the appropriately sized Tibial Tray Trial has been selected and its orientation determined, secure the trial to the resected proximal tibia using two **Headed Pins**. Choose either the posterior or anterior holes on the Tibial Tray Trial for pin placement. Insert the Headed Pins using a mallet, ensuring they are seated flush with the surface of the trial. Forceps or optional Headed Pin holders may be used to assist in holding the pins during insertion (Figure 30).

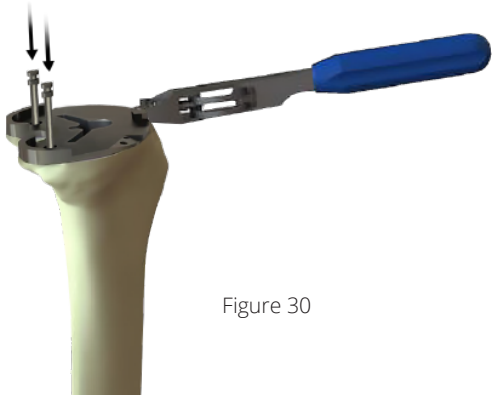
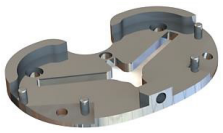


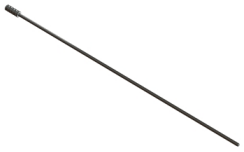
Figure 30

33. Tibial Tray Trial
M-3211-000X



34. Tibial Tray Trial Handle
M-3220-5011

35. Alignment Rod
M-3120-5028



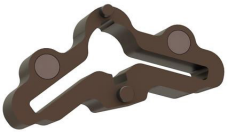
36. Headed Pin
M-3220-5015

Once pinned, place the **Tibial Broach Guide** onto the **Tibial Tray Trial** (Figure 31). Impact the Tibial Keel Broach though the Tibial Tibial Broach Guide, and into the proximal tibia for the preparation of the tibial keel (Figure 32). Be sure to impact until the Tibial Keel Broach reaches a positive stop with the Tibial Tray.

Figure 31

Figure 32

37. Tibial Broach Guide
M-3220-5019



38. Tibial Keel Broach
M-3220-5055

5. Patellar Preparation

5.1 Onset Patella Preparation:

Evert the patella. Measure and record the thickness of the patella using the **Vernier Caliper** (Figure 33). Clamp the patella using the **Patellar Resection Clamp** to perform the resection (Figure 34). Set resection depth to match the thickness of the selected patella size as shown in Table 1 below and perform resection with the Saw Blade.

Figure 33

Figure 34

Table 1: Onset Patella Size Guide

Size	29mm	32mm	35mm	38mm	41mm
Diameter (mm)	29	32	35	38	41
Thickness (mm)	8	8	9	9	10

Select the proper **Patellar Drill Guide** size and assemble onto the **Patellar Drill** and **Cement Clamp** to assist with the tri-peg drilling (Figure 35). Once in the proper position, drill into the tri-peg holes using the **Patellar Drill** (Figure 36).

Figure 35

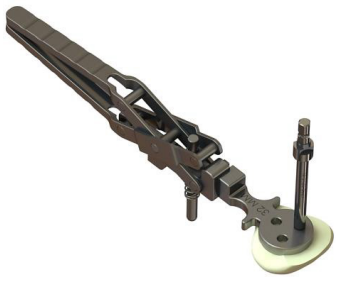


Figure 36

39. Vernier Caliper
M-3420-5008

40. Patellar Resection Clamp
M-3420-5000

41. Patellar Drill Guide
M-3420-500X

42. Patellar Drill and Cement Clamp
M-3420-5001

43. Patellar Drill
M-3120-5027

Remove the drill guide. The patella should now have the tri-peg holes (Figure 37).

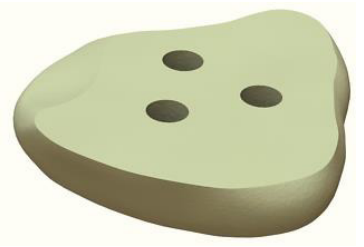


Figure 37

The **Patellar Trial** can now be positioned for use with final trialing (Figure 38).

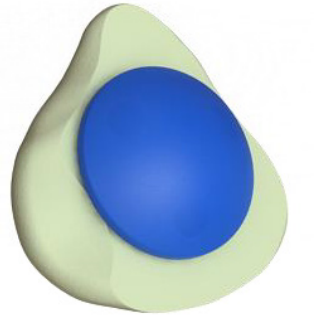


Figure 38

44. Patellar Trial
M-3411-00X0

6. Final Trial Reduction:

Select the appropriate **Tibial Insert Trial** and perform the final trial reduction with all the components in place. Put the knee through a full range of motion to check balancing and stability of the knee joint (Figure 39).

Figure 39

6.1 Trial Removal:

When the surgeon is satisfied and the joint has been thoroughly examined for range of motion/balance, the trials may be removed. Utilize the Slaphammer to remove the Femoral Trial from the femur and the Headed Pins from the Tibial Tray Trial. Prepare the bone for implantation by thoroughly cleaning all the surfaces.

45. CR Tibial Insert Trial
M-3311-10XX

46. UC Tibial Insert Trial
M-3311-40XX

47. PS Tibial Insert Trial
M-3311-20XX

7. Implant Fixation:

Prepare the cement and impact the components into place. First, attach the Modular Handle to the **Baseplate Impactor** and impact the Tibial implant into place (Figure 40). Remove excess cement.

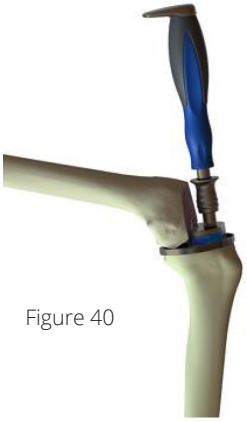


Figure 40

Next, attach the **Femoral Driver** to the Femoral component and impact the implant into place. (Figure 41) Remove the Femoral Driver by turning the knob counterclockwise and squeezing the two prongs to disengage from the implant. Next, attach the Modular Handle to the **Femoral Impactor** and finish any additional femoral impacting required.

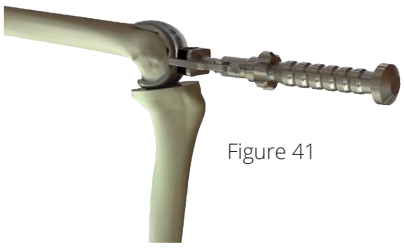


Figure 41

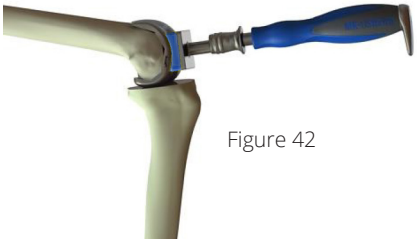


Figure 42

Utilize the **Patellar Cement Clamp** to clamp the patella until cement has fully hardened (Figure 42). Check the contact and stability of the bone/ implant couple. Measure the thickness of the bone/implant couple to verify the original patellar A-P thickness is maintained.

Figure 43

48. Baseplate Impactor
M-3220-5053

49. Femoral Driver
M-3120-5026

50. Femoral Impactor
M-3120-5050

51. Patellar Cement Clamp
M-3420-5003

Once the cement has hardened, insert the Tibial Insert into the Tibial Tray with the **Tibial Insert Impactor** (Figure 44). Ensure the Tibial Insert is fully seated.

Figure 44

52. Tibial Insert Impactor
M-3320-5054

7 .1 Final Look:

fuse medical

fuse STERIZO™
TOTAL KNEE SYSTEM

IMPLANT CATALOG

STERIZO™ IMPLANTS

CR Femoral Components

CR Femoral Components

	ML (MM)	AP (MM)
Sz 1	60	38.4
Sz 2	64	42.4
Sz 3	68	46.6
Sz 4	72	50.6
Sz 5	76	54.3
Sz 6	80	58.5

Catalog No.	Description
M-3101-1101	Femoral Left, CR, Size 1
M-3101-1102	Femoral Left, CR, Size 2
M-3101-1103	Femoral Left, CR, Size 3
M-3101-1104	Femoral Left, CR, Size 4
M-3101-1105	Femoral Left, CR, Size 5
M-3101-1106	Femoral Left, CR, Size 6
M-3101-1201	Femoral Right, CR, Size 1
M-3101-1202	Femoral Right, CR, Size 2
M-3101-1203	Femoral Right, CR, Size 3
M-3101-1204	Femoral Right, CR, Size 4
M-3101-1205	Femoral Right, CR, Size 5
M-3101-1206	Femoral Right, CR, Size 6

PS Femoral Components

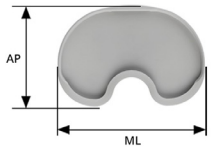
PS Femoral Components

	ML (MM)	AP (MM)
Sz 1	60	38.4
Sz 2	64	42.4
Sz 3	68	46.6
Sz 4	72	50.6
Sz 5	76	54.3
Sz 6	80	58.5

Catalog No.	Description
M-3101-2101	Femoral Left, PS, Size 1
M-3101-2102	Femoral Left, PS, Size 2
M-3101-2103	Femoral Left, PS, Size 3
M-3101-2104	Femoral Left, PS, Size 4
M-3101-2105	Femoral Left, PS, Size 5
M-3101-2106	Femoral Left, PS, Size 6
M-3101-2201	Femoral Right, PS, Size 1
M-3101-2202	Femoral Right, PS, Size 2
M-3101-2203	Femoral Right, PS, Size 3
M-3101-2204	Femoral Right, PS, Size 4
M-3101-2205	Femoral Right, PS, Size 5
M-3101-2206	Femoral Right, PS, Size 6

Tibial Trays

Tibial Trays

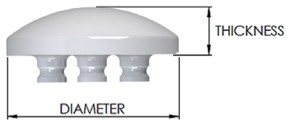


	ML (MM)	AP (MM)
Sz.0	63	41
Sz.1	66	44
Sz.2	69	47
Sz.3	72	49
Sz.4	76	52
Sz.5	80	55
Sz.6	84	58

Catalog No.	Description
M-3202-0000*	Tibial Tray, Size 0
M-3201-0001	Tibial Tray, Size 1
M-3201-0002	Tibial Tray, Size 2
M-3201-0003	Tibial Tray, Size 3
M-3201-0004	Tibial Tray, Size 4
M-3201-0005	Tibial Tray, Size 5
M-3201-0006	Tibial Tray, Size 6

Patella Inserts

Patella Inserts



THICKNESS (MM)	DIAMETER (MM)
8	29
8	32
9	35
9	38
10	41

Catalog No.	Description
M-3401-0060	Patella, 29mm
M-3401-0070	Patella, 32mm
M-3401-0080	Patella, 35mm
M-3401-0090	Patella, 38mm
M-3401-0100	Patella, 41mm

* Sterizo Modular System

STERIZO™ IMPLANTS

CR Tibial Inserts

CR Tibial Inserts

Catalog No.	Description
M-3301-1010*	Tibial Insert, CR, Size 0, 09mm
M-3301-1011	Tibial Insert, CR, Size 1, 09mm
M-3301-1012	Tibial Insert, CR, Size 2, 09mm
M-3301-1013	Tibial Insert, CR, Size 3, 09mm
M-3301-1014	Tibial Insert, CR, Size 4, 09mm
M-3301-1015	Tibial Insert, CR, Size 5, 09mm
M-3301-1016	Tibial Insert, CR, Size 6, 09mm
M-3301-1020*	Tibial Insert, CR, Size 0, 11mm
M-3301-1021	Tibial Insert, CR, Size 1, 11mm
M-3301-1022	Tibial Insert, CR, Size 2, 11mm
M-3301-1023	Tibial Insert, CR, Size 3, 11mm
M-3301-1024	Tibial Insert, CR, Size 4, 11mm
M-3301-1025	Tibial Insert, CR, Size 5, 11mm
M-3301-1026	Tibial Insert, CR, Size 6, 11mm
M-3301-1030*	Tibial Insert, CR, Size 0, 13mm
M-3301-1031	Tibial Insert, CR, Size 1, 13mm
M-3301-1032	Tibial Insert, CR, Size 2, 13mm
M-3301-1033	Tibial Insert, CR, Size 3, 13mm
M-3301-1034	Tibial Insert, CR, Size 4, 13mm
M-3301-1035	Tibial Insert, CR, Size 5, 13mm
M-3301-1036	Tibial Insert, CR, Size 6, 13mm
M-3301-1040*	Tibial Insert, CR, Size 0, 15mm
M-3301-1041	Tibial Insert, CR, Size 1, 15mm
M-3301-1042	Tibial Insert, CR, Size 2, 15mm
M-3301-1043	Tibial Insert, CR, Size 3, 15mm
M-3301-1044	Tibial Insert, CR, Size 4, 15mm
M-3301-1045	Tibial Insert, CR, Size 5, 15mm
M-3301-1046	Tibial Insert, CR, Size 6, 15mm
M-3301-1050*	Tibial Insert, CR, Size 0, 18mm
M-3301-1051	Tibial Insert, CR, Size 1, 18mm
M-3301-1052	Tibial Insert, CR, Size 2, 18mm
M-3301-1053	Tibial Insert, CR, Size 3, 18mm
M-3301-1054	Tibial Insert, CR, Size 4, 18mm
M-3301-1055	Tibial Insert, CR, Size 5, 18mm
M-3301-1056	Tibial Insert, CR, Size 6, 18mm

UC Tibial Inserts

UC Tibial Inserts

Catalog No.	Description
M-3301-4010*	Tibial Insert, UC, Size 0, 09mm
M-3301-4011	Tibial Insert, UC, Size 1, 09mm
M-3301-4012	Tibial Insert, UC, Size 2, 09mm
M-3301-4013	Tibial Insert, UC, Size 3, 09mm
M-3301-4014	Tibial Insert, UC, Size 4, 09mm
M-3301-4015	Tibial Insert, UC, Size 5, 09mm
M-3301-4016	Tibial Insert, UC, Size 6, 09mm
M-3301-4020*	Tibial Insert, UC, Size 0, 11mm
M-3301-4021	Tibial Insert, UC, Size 1, 11mm
M-3301-4022	Tibial Insert, UC, Size 2, 11mm
M-3301-4023	Tibial Insert, UC, Size 3, 11mm
M-3301-4024	Tibial Insert, UC, Size 4, 11mm
M-3301-4025	Tibial Insert, UC, Size 5, 11mm
M-3301-4026	Tibial Insert, UC, Size 6, 11mm
M-3301-4030*	Tibial Insert, UC, Size 0, 13mm
M-3301-4031	Tibial Insert, UC, Size 1, 13mm
M-3301-4032	Tibial Insert, UC, Size 2, 13mm
M-3301-4033	Tibial Insert, UC, Size 3, 13mm
M-3301-4034	Tibial Insert, UC, Size 4, 13mm
M-3301-4035	Tibial Insert, UC, Size 5, 13mm
M-3301-4036	Tibial Insert, UC, Size 6, 13mm
M-3301-4040*	Tibial Insert, UC, Size 0, 15mm
M-3301-4041	Tibial Insert, UC, Size 1, 15mm
M-3301-4042	Tibial Insert, UC, Size 2, 15mm
M-3301-4043	Tibial Insert, UC, Size 3, 15mm
M-3301-4044	Tibial Insert, UC, Size 4, 15mm
M-3301-4045	Tibial Insert, UC, Size 5, 15mm
M-3301-4046	Tibial Insert, UC, Size 6, 15mm
M-3301-4050*	Tibial Insert, UC, Size 0, 18mm
M-3301-4051	Tibial Insert, UC, Size 1, 18mm
M-3301-4052	Tibial Insert, UC, Size 2, 18mm
M-3301-4053	Tibial Insert, UC, Size 3, 18mm
M-3301-4054	Tibial Insert, UC, Size 4, 18mm
M-3301-4055	Tibial Insert, UC, Size 5, 18mm
M-3301-4056	Tibial Insert, UC, Size 6, 18mm

* Sterizo Modular System

STERIZO™ IMPLANTS

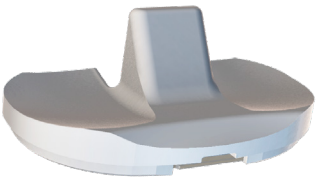
PS Tibial Inserts

PS Tibial Inserts

Catalog No.	Description
M-3301-2010*	Tibial Insert, PS, Size 0, 09mm
M-3301-2011	Tibial Insert, PS, Size 1, 09mm
M-3301-2012	Tibial Insert, PS, Size 2, 09mm
M-3301-2013	Tibial Insert, PS, Size 3, 09mm
M-3301-2014	Tibial Insert, PS, Size 4, 09mm
M-3301-2015	Tibial Insert, PS, Size 5, 09mm
M-3301-2016	Tibial Insert, PS, Size 6, 09mm
M-3301-2020*	Tibial Insert, PS, Size 0, 11mm
M-3301-2021	Tibial Insert, PS, Size 1, 11mm
M-3301-2022	Tibial Insert, PS, Size 2, 11mm
M-3301-2023	Tibial Insert, PS, Size 3, 11mm
M-3301-2024	Tibial Insert, PS, Size 4, 11mm
M-3301-2025	Tibial Insert, PS, Size 5, 11mm
M-3301-2026	Tibial Insert, PS, Size 6, 11mm
M-3301-2030*	Tibial Insert, PS, Size 0, 13mm
M-3301-2031	Tibial Insert, PS, Size 1, 13mm
M-3301-2032	Tibial Insert, PS, Size 2, 13mm
M-3301-2033	Tibial Insert, PS, Size 3, 13mm
M-3301-2034	Tibial Insert, PS, Size 4, 13mm
M-3301-2035	Tibial Insert, PS, Size 5, 13mm
M-3301-2036	Tibial Insert, PS, Size 6, 13mm
M-3301-2040*	Tibial Insert, PS, Size 0, 15mm
M-3301-2041	Tibial Insert, PS, Size 1, 15mm
M-3301-2042	Tibial Insert, PS, Size 2, 15mm
M-3301-2043	Tibial Insert, PS, Size 3, 15mm
M-3301-2044	Tibial Insert, PS, Size 4, 15mm
M-3301-2045	Tibial Insert, PS, Size 5, 15mm
M-3301-2046	Tibial Insert, PS, Size 6, 15mm
M-3301-2050*	Tibial Insert, PS, Size 0, 18mm
M-3301-2051	Tibial Insert, PS, Size 1, 18mm
M-3301-2052	Tibial Insert, PS, Size 2, 18mm
M-3301-2053	Tibial Insert, PS, Size 3, 18mm
M-3301-2054	Tibial Insert, PS, Size 4, 18mm
M-3301-2055	Tibial Insert, PS, Size 5, 18mm
M-3301-2056	Tibial Insert, PS, Size 6, 18mm

PS+ Tibial Inserts

PS+ Tibial Inserts



Catalog No.	Description
M-3301-5010*	Tibial Insert, PS+, Size 0, 09mm
M-3301-5011	Tibial Insert, PS+, Size 1, 09mm
M-3301-5012	Tibial Insert, PS+, Size 2, 09mm
M-3301-5013	Tibial Insert, PS+, Size 3, 09mm
M-3301-5014	Tibial Insert, PS+, Size 4, 09mm
M-3301-5015	Tibial Insert, PS+, Size 5, 09mm
M-3301-5016	Tibial Insert, PS+, Size 6, 09mm
M-3301-5020*	Tibial Insert, PS+, Size 0, 11mm
M-3301-5021	Tibial Insert, PS+, Size 1, 11mm
M-3301-5022	Tibial Insert, PS+, Size 2, 11mm
M-3301-5023	Tibial Insert, PS+, Size 3, 11mm
M-3301-5024	Tibial Insert, PS+, Size 4, 11mm
M-3301-5025	Tibial Insert, PS+, Size 5, 11mm
M-3301-5026	Tibial Insert, PS+, Size 6, 11mm
M-3301-5030*	Tibial Insert, PS+, Size 0, 13mm
M-3301-5031	Tibial Insert, PS+, Size 1, 13mm
M-3301-5032	Tibial Insert, PS+, Size 2, 13mm
M-3301-5033	Tibial Insert, PS+, Size 3, 13mm
M-3301-5034	Tibial Insert, PS+, Size 4, 13mm
M-3301-5035	Tibial Insert, PS+, Size 5, 13mm
M-3301-5036	Tibial Insert, PS+, Size 6, 13mm
M-3301-5040*	Tibial Insert, PS+, Size 0, 15mm
M-3301-5041	Tibial Insert, PS+, Size 1, 15mm
M-3301-5042	Tibial Insert, PS+, Size 2, 15mm
M-3301-5043	Tibial Insert, PS+, Size 3, 15mm
M-3301-5044	Tibial Insert, PS+, Size 4, 15mm
M-3301-5045	Tibial Insert, PS+, Size 5, 15mm
M-3301-5046	Tibial Insert, PS+, Size 6, 15mm
M-3301-5050*	Tibial Insert, PS+, Size 0, 18mm
M-3301-5051	Tibial Insert, PS+, Size 1, 18mm
M-3301-5052	Tibial Insert, PS+, Size 2, 18mm
M-3301-5053	Tibial Insert, PS+, Size 3, 18mm
M-3301-5054	Tibial Insert, PS+, Size 4, 18mm
M-3301-5055	Tibial Insert, PS+, Size 5, 18mm
M-3301-5056	Tibial Insert, PS+, Size 6, 18mm

* Sterizo Modular System

fuse medical

fuse STERIZO™
TOTAL KNEE SYSTEM

INSTRUMENT CATALOG

STERIZO™ INSTRUMENTS

Tray 1 Instruments

Catalog No.	Dimensions
	Diameter x Length
M-3120-5005	Distal Femoral Alignment Guide
M-3120-5050	Femoral Impactor
M-3120-5006	Distal Femoral Cutting Guide
M-3120-5054	CR Femur Lug Drill
M-3120-5027	Patellar Drill
M-3120-5004	Pin Driver
M-3220-5015	Headed Pin
M-3120-5040	3.2mm Twist Drill
M-3120-5003	Smooth Pin
M-3120-5000	Femoral IM Drill
M-3420-5001	Patellar Drill and Cement Clamp
M-3120-5026	Femoral Driver
M-3420-5008	Vernier Caliper
M-3220-5005	Slaphammer
M-3120-5016	Blade Gauge
M-3120-5001	Intramedullary (IM) Rod
M-3411-0060	Patellar Trial, 29mm
M-3411-0070	Patellar Trial, 32mm
M-3411-0080	Patellar Trial, 35mrn
M-3411-0090	Patellar Trial, 38mm
M-3411-0100	Patellar Trial, 41mm
M-3420-5003	Patellar Cement Clamp
G910100	Modular Handle
M-3420-5002	Patellar Drill Guide 29mm
M-3420-5005	Patellar Drill Guide 32mm
M-3420-5006	Patellar Drill Guide 35mm
M-3420-5007	Patellar Drill Guide 38mm
M-3420-5041	Patellar Drill Guide 41mm
M-3120-5002	Femoral IM Alignment Guide
M-3120-5008	Femoral Sizer, Anterior
M-3120-5010	Femoral 4 in 1 Cut Guide Anterior Ref, Size 1
M-3120-5011	Femoral 4 in 1 Cut Guide Anterior Ref, Size 2
M-3120-5012	Femoral 4 in 1 Cut Guide Anterior Ref, Size 3
M-3120-5013	Femoral 4 in 1 Cut Guide Anterior Ref, Size 4
M-3120-5014	Femoral 4 in 1 Cut Guide Anterior Ref, Size 5
M-3120-5015	Femoral 4 in 1 Cut Guide Anterior Ref, Size 6
M-3120-5009	Femoral Sizer, Posterior
M-3120-5031	Femoral 4 in 1 Cut Guide Posterior Ref, Size 1
M-3120-5032	Femoral 4 in 1 Cut Guide Posterior Ref, Size 2
M-3120-5033	Fernoral 4 in 1 Cut Guide Posterior Ref, Size 3
M-3120-5034	Femoral 4 in 1 Cut Guide Posterior Ref, Size 4
M-3120-5035	Femoral 4 in 1 Cut Guide Posterior Ref, Size 5
M-3120-5036	Femoral 4 in 1 Cut Guide Posterior Ref, Size 6

Tray 2 Instruments

Catalog No.	Dimensions
	Diameter x Length
M-3220-5003	Tibial IM Guide
M-3220-5055	Tibial Keel Broach
M-3220-5016	Tibial EM Shaft, Short
M-3220-5016-01	Tibial EM Shaft, Long
M-3220-5000	Tibial Cutting Guide, Left
M-3220-5001	Tibial Cutting Guide, Right
M-3220-5053	Baseplate Impactor
M-3320-5054	Tibial Insert Impactor
M-3120-5007	Pin Extractor
M-3211-1000-R*	Tibial Tray Trial Size 0
M-3211-0001	Tibial Tray Trial Size 1
M-3211-0002	Tibial Tray Trial Size 2
M-3211-0003	Tibial Tray Trial Size 3
M-3211-0004	Tibial Tray Trial Size 4
M-3211-0005	Tibial Tray Trial Size 5
M-3211-0006	Tibial Tray Trial Size 6
M-3220-5007	Gap Gauge Insert, llmrn
M-3220-5008	Gap Gauge Insert, 13mm
M-3220-5009	Gap Gauge Insert, 15mm
M-3220-5010	Gap Gauge Insert, 18mm
M-3220-5006	Gap Gauge
M-3220-5020	Tibial EM Shaft, Spiked
M-3220-5002	Tibial EM Alignment Guide
M-3220-5019	Tibial Broach Guide
M-3120-5028	Alignment Rod
M-3420-5000	Patellar Resection Clamp
M-3220-5004	Tibial Stylus
M-3220-5011	Tibial Tray Trial Handle
M-3220-5056	Tibial Alignment Rod Holder

* Sterizo Modular System

STERIZO™ INSTRUMENTS

Tray 3 Instruments

Catalog No.	Dimensions
	Diameter x Length
M-3111-2101	PS Femoral Trial Size 1, Left
M-3111-2102	PS Femoral Trial Size 2, Left
M-3111-2103	PS Femoral Trial Size 3, Left
M-3111-2104	PS Femoral Trial Size 4, Left
M-3111-2105	PS Femoral Trial Size 5, Left
M-3111-2106	PS Femoral Trial Size 6, Left
M-3120-5017	PS Notching Jig Size 1
M-3120-5018	PS Notching Jig Size 2
M-3120-5019	PS Notching Jig Size 3
M-3120-5020	PS Notching Jig Size 4
M-3120-5021	PS Notching Jig Size 5
M-3120-5022	PS Notching Jig Size 6
M-3111-2201	PS Femoral Trial Size 1, Right
M-3111-2202	PS Femoral Trial Size 2, Right
M-3111-2203	PS Femoral Trial Size 3, Right
M-3111-2204	PS Femoral Trial Size 4, Right
M-3111-2205	PS Femoral Trial Size 5, Right
M-3111-2206	PS Femoral Trial Size 6, Right
M-3111-1101	CR Femoral Trial Size 1, Left
M-3111-1102	CR Femoral Trial Size 2, Left
M-3111-1103	CR Femoral Trial Size 3, Left
M-3111-1104	CR Femoral Trial Size 4, Left
M-3111-1105	CR Femoral Trial Size 5, Left
M-3111-1106	CR Femoral Trial Size 6, Left
M-3111-1201	CR Femoral Trial Size 1, Right
M-3111-1202	CR Femoral Trial Size 2, Right
M-3111-1203	CR Femoral Trial Size 3, Right
M-3111-1204	CR Femoral Trial Size 4, Right
M-3111-1205	CR Femoral Trial Size 5, Right
M-3111-1206	CR Femoral Trial Size 6, Right

Tray 4 Instruments (UC Trials)

Catalog No.	Dimensions
	Diameter x Length
G910100	Modular Handle
M-3311-4010*	UC Tibial Insert Trial Size 0, 09mm
M-3311-4011	UC Tibial Insert Trial Size 1, 09mm
M-3311-4012	UC Tibial Insert Trial Size 2, 09mm
M-3311-4013	UC Tibial Insert Trial Size 3, 09mm
M-3311-4014	UC Tibial Insert Trial Size 4, 09mm
M-3311-4015	UC Tibial Insert Trial Size 5, 09rnm
M-3311-4016	UC Tibial Insert Trial Size 6, 09mm
M-3311-4020*	UC Tibial Insert Trial Size 0, llmm
M-3311-4021	UC Tibial Insert Trial Size 1, llmm
M-3311-4022	UC Tibial Insert Trial Size 2, llmm
M-3311-4023	UC Tibial Insert Trial Size 3, 11mm
M-3311-4024	UC Tibial Insert Trial Size 4, 11mm
M-3311-4025	UC Tibial Insert Trial Size 5, llmm
M-3311-4026	UC Tibial Insert Trial Size 6, llmm
M-3311-4030*	UC Tibial Insert Trial Size 0, 13mm
M-3311-4031	UC Tibial Insert Trial Size 1, 13mm
M-3311-4032	UC Tibial Insert Trial Size 2, 13mm
M-3311-4033	UC Tibial Insert Trial Size 3, 13mrn
M-3311-4034	UC Tibial Insert Trial Size 4, 13rnnn
M-3311-4035	UC Tibial Insert Trial Size 5, 13mm
M-3311-4036	UC Tibial Insert Trial Size 6, 13mm
M-3311-4040*	UC Tibial Insert Trial Size 0, 15mm
M-3311-4041	UC Tibial Insert Trial Size 1, 15mrn
M-3311-4042	UC Tibial Insert Trial Size 2, 15rnm
M-3311-4043	UC Tibial Insert Trial Size 3, 15mm
M-3311-4044	UC Tibial Insert Trial Size 4, 15mm
M-3311-4045	UC Tibial Insert Trial Size 5, 15mm
M-3311-4046	UC Tibial Insert Trial Size 6, 15mm
M-3311-4050*	UC Tibial Insert Trial Size 0, 18mm
M-3311-4051	UC Tibial Insert Triat Size 1, 18mrn
M-3311-4052	UC Tibial Insert Trial Size 2, 18mm
M-3311-4053	UC Tibial Insert Trial Size 3, 18mm
M-3311-4054	UC Tibial Insert Trial Size 4, 18mm
M-3311-4055	UC Tibial Insert Trial Size 5, 18mrn
M-3311-4056	UC Tibial Insert Trial Size 6, 18mm

* Sterizo Modular System

STERIZO™ INSTRUMENTS

Tray 4 Instruments (PS Trials)

Catalog No.	Dimensions
	Diameter x Length
M-3120-5051	PS Notching Inserter
M-3120-5023	PS Reamer
M-3120-5052	PS Punch
M-3311-2010*	PS Tibial Insert Trial Size 0, 09mm
M-3311-2011	PS Tibial Insert Trial Size 1, 09mm
M-3311-2012	PS Tibial Insert Trial Size 2, 09mm
M-3311-2013	PS Tibial Insert Trial Size 3, 09mm
M-3311-2014	PS Tibial Insert Trial Size 4, 09mm
M-3311-2015	PS Tibial Insert Trial Size 5, 09mm
M-3311-2016	PS Tibial Insert Trial Size 6, 09mm
M-3311-2020*	PS Tibial Insert Trial Size 0, 11mrn
M-3311-2021	PS Tibial Insert Trial Size 1, 11mm
M-3311-2022	PS Tibial Insert Trial Size 2, 11mm
M-3311-2023	PS Tibial Insert Trial Size 3, 11mm
M-3311-2024	PS Tibial Insert Trial Size 4, 11mm
M-3311-2025	PS Tibial Insert Trial Size 5, 11mm
M-3311-2026	PS Tibial Insert Trial Size 6, 11mm
M-3311-2030*	PS Tibial Insert Trial Size 0, 13mm
M-3311-2031	PS Tibial Insert Trial Size 1, 13mm
M-3311-2032	PS Tibial Insert Trial Size 2, 13mm
M-3311-2033	PS Tibial Insert Trial Size 3, 13mm
M-3311-2034	PS Tibial Insert Trial Size 4, 13mm
M-3311-2035	PS Tibia! Insert Trial Size 5, 13mm
M-3311-2036	PS Tibial Insert Trial Size 6, 13mm
M-3311-2040*	PS Tibial Insert Trial Size 0, 15mm
M-3311-2041	PS Tibial Insert Trial Size 1, 15mm
M-3311-2042	PS Tibial Insert Trial Size 2, 15mm
M-3311-2043	PS Tibial Insert Trial Size 3, 15mm
M-3311-2044	PS Tibial Insert Trial Size 4, 15mm
M-3311-2045	PS Tibial Insert Trial Size 5, 15mm
M-3311-2046	PS Tibial Insert Trial Size 6, 15mm
M-3311-2050*	PS Tibial Insert Trial Size 0, 18mm
M-3311-2051	PS Tibial Insert Trial Size 1,18mm
M-3311-2052	PS Tibial Insert Trial Size 2, 18mm
M-3311-2053	PS Tibial Insert Trial Size 3, 18mm
M-3311-2054	PS Tibial Insert Trial Size 4, 18mm
M-3311-2055	PS Tibial Insert Trial Size 5, 18mm
M-3311-2056	PS Tibial Insert Trial Size 6, 18mm

Tray 4 Instruments (CR Trials)

Catalog No.	Dimensions
	Diameter x Length
M-3311-1011	CR Tibial Insert Trial Size 1, 09mm
M-3311-1012	CR Tibial Insert Trial Size 2, 09mm
M-3311-1013	CR Tibial Insert Trial Size 3, 09mm
M-3311-1014	CR Tibial Insert Trial Size 4, 09mm
M-3311-1015	CR Tibial Insert Trial Size 5, 09mm
M-3311-1016	CR Tibial Insert Trial Size 6, 09mm
M-3311-1021	CR Tibial Insert Trial Size 1, 11mm
M-3311-1022	CR Tibial Insert Trial Size 2, 11mm
M-3311-1023	CR Tibial Insert Trial Size 3, 11mm
M-3311-1024	CR Tibial Insert Trial Size 4, 11mm
M-3311-1025	CR Tibial Insert Trial Size 5, llmm
M-3311-1026	CR Tibial Insert Triat Size 6, llmm
M-3311-1031	CR Tibial Insert Trial Size 1, 13mm
M-3311-1032	CR Tibial Insert Trial Size 2, 13mm
M-3311-1033	CR Tibial Insert Trial Size 3, 13mm
M-3311-1034	CR Tibial Insert Trial Size 4, 13mm
M-3311-1035	CR Tibial Insert Trial Size 5, 13mm
M-3311-1036	CR Tibial Insert Trial Size 6, 13mm
M-3311-1041	CR Tibial Insert Trial Size 1, 15mm
M-3311-1042	CR Tibial Insert Triat Size 2, 15mm
M-3311-1043	CR Tibial Insert Trial Size 3, 15mm
M-3311-1044	CR Tibial Insert Trial Size 4, 15mm
M-3311-1045	CR Tibial Insert Trial Size 5, 15mm
M-3311-1046	CR Tibial Insert Trial Size 6, 15mm
M-3311-1051	CR Tibial Insert Trial Size 1,18mm
M-3311-1052	CR Tibial Insert Trial Size 2, 18mm
M-3311-1053	CR Tibial Insert Trial Size 3, 18mm
M-3311-1054	CR Tibial Insert Trial Size 4, 18mm
M-3311-1055	CR Tibial Insert Trial Size 5, 18mrn
M-3311-1056	CR Tibial Insert Trial Size 6, 18mm

* Sterizo Modular System

fuse medical

fuse STERIZO™
TOTAL KNEE SYSTEM

SAFETY INFORMATION

10. Warnings and Precautions:

Refer to the STERIZO Total Knee System Instructions For Use for warning, precautions, potential adverse effects, indications and contraindications, and other essential information.

REMOVAL/REVISION OF DEVICE
Intentional removal of a total knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes, and cautious extraction forces. For further information about removal or revision of device please contact Fuse Medical at the address or telephone number below.

Caution: Federal law (USA) restricts this device to sale, distribution, or use by or on the order of a physician. Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Fuse Medical, 4343 Sigma Rd., Suite 500 Farmers Branch, TX 75244 (469) 862-3030.

11. Sterility Parameters:

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. STERIZO instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using STERIZO instruments or instrument cases, please bring this to Fuse Medical or Fuse Medical's distributor's attention when you return them (Instruments returned to Fuse Medical or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provide guidelines for return or contact Fuse Medical or your distributor for further instruction).

Unless supplied sterile, instruments must be thoroughly cleaned and sterilized prior to surgical use. Set forth below is a recommended minimum cycle for steam sterilization that has been validated under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below.

Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended. The following cycle parameters are the minimum for instrument cases up to 25 lbs (11 kgs).

11. Sterility Parameters (Cont.):

Steam Autoclave Cycle Parameters*

GRAVITY DISPLACEMENT STERILIZER (Full Cycle)
Double Wrapped in a FDA cleared 1-ply wrap
Temperature 270° F (132° C)
Exposure Time 15 minutes
Drying time 55 minutes

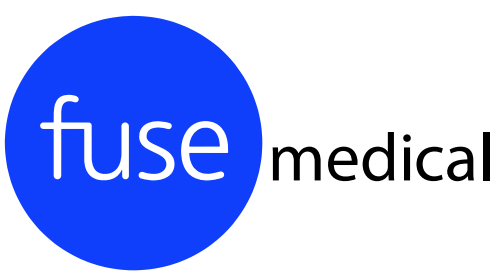
PRE-VACUUMED STERILIZER {HI-VAC)
Double Wrapped in a FDA cleared 1-ply wrap
Temperature 270° F (132° C)
Exposure Time 4 minutes
Drying time 30 minutes

*Validated under laboratory conditions; however, these cycles must be re-validated by the end-user to ensure that sterility can be achieved on site.

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Comments regarding the use of this device can be directed to

Attn: Customer Service, Fuse Medical, 4343 Sigma Rd., Suite 500
Farmers Branch, TX 75244 or info@fusemedical.com



Fuse Medical, Inc.
4343 Sigma Rd., Suite 500
Farmers Branch, TX 75244
P: 469-862-3030
F: 469-862-3035
www.fusemedical.com

SXT-S-001 Rev B
DC-0474