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STERIZO™

Primary Knee System

Surgical Technique

SXT-S-001 REV A
DCR# DC-0043
Effective Date 11/27/2019

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STERIZO Total Knee System

Stability

Choose your constraint style – Cruciate Retained, Ultra Congruent/Anterior Stabilized, or Posterior Stabilized, 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. Strength in quality. Strength in longevity. Strength in patient outcomes and 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 utilization.

High Flex Design

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

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, posttraumatic 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. Templates are available to estimate implant size. 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 hers medical training and experience.

3. Femoral Preparation:

Utilize the starting Three Step Drill to enter the femoral canal (Figure 1). The 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 – either 3, 5, 7, or 9 degrees. **Be sure to note Left or Right**

Insert the T-Handle Femoral IM Rod attached to the Femoral IM Alignment Guide ensuring the guide is contacting the distal femur (Figure 2).

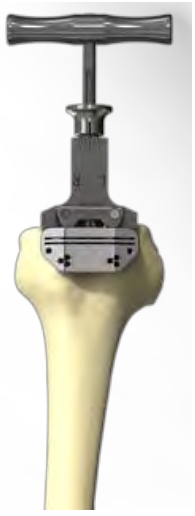


Figure 2

1. Three Step Drill
   M-3120-5000

2. Femoral IM Rod
   M-3120-5001

3. Femoral IM
   Alignment Guide
   M-3120-5002

4. Distal Femoral
   Cutting Block
   M-3120-5006

5. Distal Femoral
   Alignment Guide
   M-3120-5005

3.2 Distal Femoral Cut:

Attach the Distal Femoral Cutting Block to the Distal Femoral Alignment Guide. Using the Quick Pin Driver, pin the cutting block in place assuring that the Femoral Alignment Guide is flush with the distal femur (Figure 3). Remove alignment guide.

Figure 3

Use a .05" (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) Cutting block may be moved on pins +/-2mm

Figure 4

After completion of the distal femoral cut, remove cutting block and leave pins in place if desired to address additional distal femoral resection if needed during gap balancing, or remove pins with pin extractor (Figure 5).

Figure 5

6. Long Pin
   M-3120-5003

7. Quick Pin Driver
   M-3120-5004

8. Pin Extractor
   M-3120-5007

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

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 posterior condyles are deficient, align pins with 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

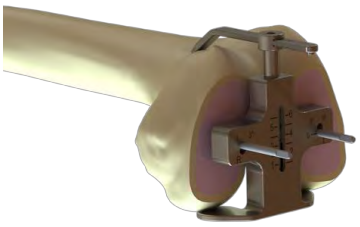


Figure 7

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 0.

Figure 8

Reference the sizing guide to establish the correct femoral component size (0-6). 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 4-in-1 Femoral A/P Chamfer Cutting Block based on femur sizer measurement.

3.4 4-in-1 Cutting Block:

After establishing the appropriate size, choose the corresponding Femoral A/P Chamfer Cutting Block and place it in the pre-drilled holes on the distal femur. Impact the block flush onto the distal femur. Check the 4-in-1 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

Once confirmed, pin the Femoral A/P Chamfer Cutting Block through both medial and lateral pin holes to secure the block (Figure 10). Resect the femur with the 1.27mm Saw Blade beginning with the anterior cut slot, then moving to the posterior slot, then anterior and posterior chamfers.

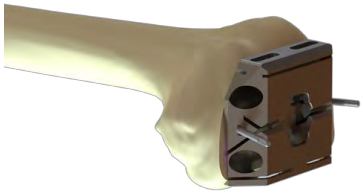


Figure 10

3.5 CR Femoral Trial Preparation:

Place the appropriate size CR Femoral Trial component onto the lock-on Femoral Impactor; align and impact onto the femur until the Femoral Trial is fully seated (Figure 11). Align the CR Femoral Trial and drill distal femoral lug holes with the CR Drill (Figure 12).

Figure 11

Figure 12

The Femoral Trial may be removed with the Slaphammer by inserting the tip of the Slaphammer into the center of the Femoral Trial and rotate 90° to engage (Figure 13).

Figure 13

10. Femoral A/P Chamfer Cutting Block C/N varies by size

11. Blade Gauge M-3120-5016

12. CR Femoral Trial C/N varies by size

13. Femoral Impactor M-3120-5026

14. CR Drill M-3120-5054

15. Slaphammer M-3220-5005

3.6 PS Femoral Preparation:

Place the PS Notch Cutting Block onto the resected femur using the Modular PS Notch Inserter with the Modular Handle attached (Figure 14).

Figure 14

Align the PS Notch Cutting Block unit and pin into place to provide room for the PS box. Use the PS Reamer to mill out the posterior slot first followed by the anterior slot (Figure 15/16).

Step 1: Posterior

Figure 15

Step 2: Anterior

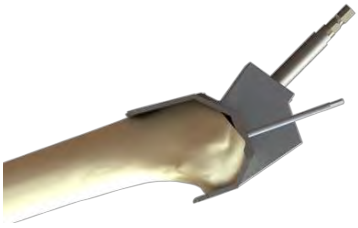


Figure 16

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 17/18). Remove the PS Notch Cutting Block by removing the pins with the Pin Extractor.

Step 1: Posterior

Figure 17

Step 2: Anterior

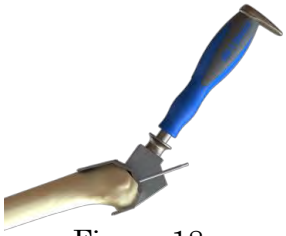


Figure 18

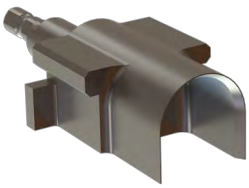
16. PS Notch Cutting Block C/N varies by size

17. Modular PS Notch Inserter M-3120-5051

18. Modular Handle G90100

19. PS Reamer M-3120-5023

20. Modular PS Punch Broach M-3120-5052



3.7 PS Femoral Trial Preparation:

Place the appropriate size PS Femoral Trial component onto the lock-on Femoral Impactor; align and impact onto the femur until the Femoral Trial is fully seated (Figure 19).

Figure 19

The Femoral Trial may be removed with the Slaphammer by inserting the tip of the Slaphammer into the center of the Femoral Trial and rotate 90° to engage (Figure 20).

Figure 20

21. PS Femoral Trial
    C/N varies by size

22. Femoral Impactor
    M-3120-5026

23. Slaphammer
    M-3220-5005

4. Tibial Preparation

5 degrees 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 21

4.1 Extramedullary (EM) Tibial Resection:

Assemble the Tibial EM Alignment Guide with the left or right Tibial Cutting Block. With the knee fully flexed, place the ankle clamp over the distal tibia. Proximally, place the Tibial EM Guide against the tibia. Adjust the guide so that it is parallel to the long axis of the tibia (Figure 21).

4.2 Intramedullary (IM) Tibial Resection:

Insert the IM rod into the tibial canal. Assemble the Tibial IM Guide and allow the IM rod to pass through the isthmus of the canal (Figure 22). Position the alignment guide in order to perform a proximal tibial resection.

Figure 22

Using either the EM or IM option, place the Tibial Stylus onto the Tibial Cutting Block. The two options for positioning the Tibial Cutting Block 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 23). Resect with Saw Blade through the cut slot.

Figure 23

Altering the tibial resection thickness with the Tibial Cutting Block can be accomplished by (Figure 24);

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

Figure 24

24. Tibial Cutting Block Left/Right
    M-3220-5000
    M-3220-5001

25. Tibial EM Guide
    M-3220-5002

26. Tibial IM Guide
    M-3220-5003

27. Tibial Stylus
    M-3220-5004

If satisfied with tibial resection, remove pins with 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 spacer block (Figure 25). 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 25

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 tibial cutting block 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 posterior and not change the extension gap.

3) Flexion balanced & Extension too tight – place distal femoral cutting block onto existing pins and remove more bone on the distal femur.

28. Gap Gauge
M-3220-5006

29. Gap Gauge Insert
C/N varies by size

30. 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.

Figure 26

Attach the Tibial Baseplate Trial Handle to the Tibial Trial that best covers the proximal tibia (Figure 26). If desired, Tibial Tray Trial alignment and varus/valgus position may be checked by inserting the alignment rod into the hole on the Tibial Baseplate Trial Handle (Figure 27). Pin into place with the Headed Pins using the two posterior holes located on the Tibial Tray Trial.

Figure 27

31. Tibial Tray Trial
    C/N varies by size

32. Tibial Baseplate Trial Handle
    M-3220-5011

33. Alignment Rod
    M-3120-5028

34. Headed Pin
    M-3220-5015

Once pinned, place the Tibial Broach Guide onto the Tibial Tray Trial (Figure 28). Through the Broach Guide, impact the Keel Broach into the proximal tibia for the preparation of the tibial keel (Figure 29). Be sure to impact until the Tibial Keel Broach reaches a positive stop with the Tibial Broach Guide.

Figure 28

Depending on preference, the one-piece Tibial Keel Broach can be used, and will be removed completely. If the two-piece device is used, unscrew the Removable Keel Punch Handle from Keel Cutting Edge and leave keel in place to stabilize trial base (Figure 30).

Figure 29

Figure 30

35. Tibial Broach Guide
M-3220-5019

36. Tibial Keel Broach
M-3220-5055

37. Two Piece Tibial Keel Broach
M-3220-5012
M-3220-5013

5. Patellar Preparation

5.1 Onset Patella Preparation:

Evert the patella. Measure and record the thickness of the patella using the Vernier Caliper (Figure 31). Clamp the patella using the Patellar Resection Clamp to perform the resection (Figure 32). 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 31

Figure 32

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 Patella Drill and Cement Clamp to assist with the tri-peg drilling (Figure 33). Once in the proper position, drill into the tri-peg holes using the Patellar Drill (Figure 34).

Figure 33

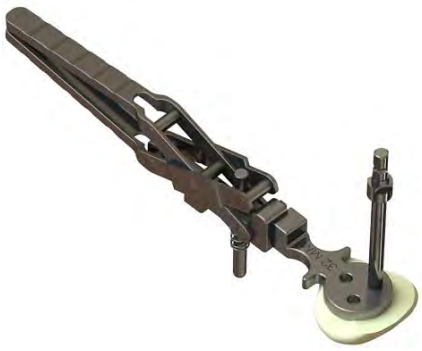


Figure 34

38. Vernier Caliper
    M-3420-5008

39. Patellar Resection Clamp
    M-3420-5000

40. Patellar Drill Guide
    C/N varies by size

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

42. Patellar Drill
    M-3120-5027

43. Patellar Trial
C/N varies by size

Remove the drill guide. The patella should now have the tri-peg holes (Figure 35).

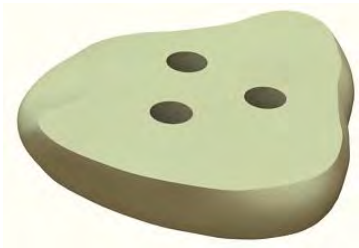


Figure 35

The Patellar Trial can now be positioned for use with final trialing (Figure 36).

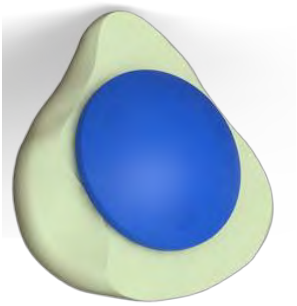


Figure 36

44. Tibial Insert Trial
C/N varies by size

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 37).

Figure 37

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 if the two-piece Tibial Keel Broach was used, thread the Removable Keel Punch Handle into the Keel Cutting Edge and remove from the proximal tibia. Prepare the bone for implantation by thoroughly cleaning all the surfaces.

7. Implant Fixation:

Prepare the cement and impact the components into place with the appropriate Modular Handle Impactor (Figure 38 & 39). Remove excess cement.

Figure 38

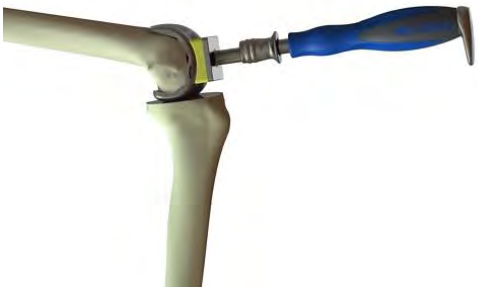
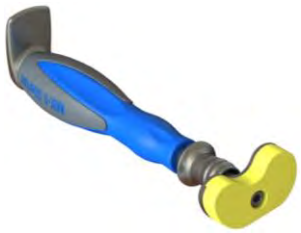


Figure 39

Utilize the Patellar Cement Clamp to clamp the patella until cement has fully hardened (Figure 40). Check 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 40

45. Tibial Baseplate Impactor – Modular
M-3220-5053
G90100



46. Femoral Driver-Modular
M-3120-5050
G90100

47. 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 41). Ensure the Tibial Insert is fully seated.

Figure 41

48. Tibial Insert Impactor-Modular M-3320-5054 G90100

7.1 Final Look:

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STERIZO™

IMPLANT CATALOG

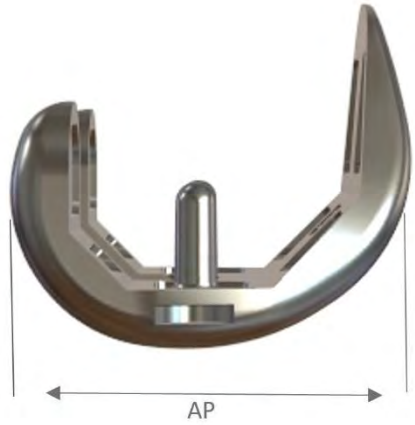
SXT-S-001 REV A
DCR# DC-0043
Effective Date 11/27/2019

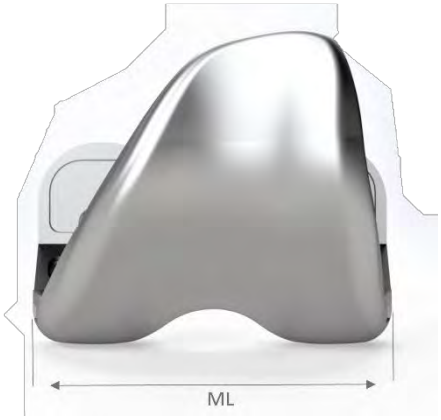
ORDERING INFORMATION

Implants

STERIZO™ FEMORAL COMPONENTS

Catalog Number	Description
M-3101-1100	CR Femur #0 Left*
M-3101-1101	CR Femur #1 Left
M-3101-1102	CR Femur #2 Left
M-3101-1103	CR Femur #3 Left
M-3101-1104	CR Femur #4 Left
M-3101-1105	CR Femur #5 Left
M-3101-1106	CR Femur #6 Left
M-3101-1200	CR Femur #0 Right*
M-3101-1201	CR Femur #1 Right
M-3101-1202	CR Femur #2 Right
M-3101-1203	CR Femur #3 Right
M-3101-1204	CR Femur #4 Right
M-3101-1205	CR Femur #5 Right
M-3101-1206	CR Femur #6 Right
M-3101-2100	PS Femur #0 Left*
M-3101-2101	PS Femur #1 Left
M-3101-2102	PS Femur #2 Left
M-3101-2103	PS Femur #3 Left
M-3101-2104	PS Femur #4 Left
M-3101-2105	PS Femur #5 Left
M-3101-2106	PS Femur #6 Left
M-3101-2200	PS Femur #0 Right*
M-3101-2201	PS Femur #1 Right
M-3101-2202	PS Femur #2 Right
M-3101-2203	PS Femur #3 Right
M-3101-2204	PS Femur #4 Right
M-3101-2205	PS Femur #5 Right
M-3101-2206	PS Femur #6 Right



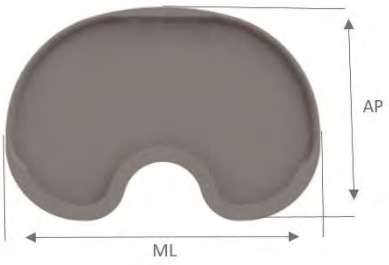


Size	ML	AP
0*	56	34.4
1	60	38.4
2	64	42.4
3	68	46.6
4	72	50.6
5	76	54.3
6	80	58.5

Implants

STERIZO™ Tibial Baseplate

Catalog Number	Description
M-3201-0000	Tibial Tray #0*
M-3201-0001	Tibial Tray #1
M-3201-0002	Tibial Tray #2
M-3201-0003	Tibial Tray #3
M-3201-0004	Tibial Tray #4
M-3201-0005	Tibial Tray #5
M-3201-0006	Tibial Tray #6



Size	0*	1	2	3	4	5	6
AP	63	66	69.1	72.2	75.7	80	84.3
ML	41	44.4	47	49.3	52.3	55.4	58.4

CR Tibial Insert

Catalog Number	Description
M-3301-1010	CR Tibial Insert #0, 9mm*
M-3301-1011	CR Tibial Insert #1, 9mm
M-3301-1012	CR Tibial Insert #2, 9mm
M-3301-1013	CR Tibial Insert #3, 9mm
M-3301-1014	CR Tibial Insert #4, 9mm
M-3301-1015	CR Tibial Insert #5, 9mm
M-3301-1016	CR Tibial Insert #6, 9mm
M-3301-1020	CR Tibial Insert #0, 11mm*
M-3301-1021	CR Tibial Insert #1, 11mm
M-3301-1022	CR Tibial Insert #2, 11mm
M-3301-1023	CR Tibial Insert #3, 11mm
M-3301-1024	CR Tibial Insert #4, 11mm
M-3301-1025	CR Tibial Insert #5, 11mm

Implants

CR Tibial Insert Cont.

M-3301-1026	CR Tibial Insert #6, 11mm
M-3301-1030	CR Tibial Insert #0, 13mm*
M-3301-1031	CR Tibial Insert #1, 13mm
M-3301-1032	CR Tibial Insert #2, 13mm
M-3301-1033	CR Tibial Insert #3, 13mm
M-3301-1034	CR Tibial Insert #4, 13mm
M-3301-1035	CR Tibial Insert #5, 13mm
M-3301-1036	CR Tibial Insert #6, 13mm
M-3301-1040	CR Tibial Insert #0, 15mm*
M-3301-1041	CR Tibial Insert #1, 15mm
M-3301-1042	CR Tibial Insert #2, 15mm
M-3301-1043	CR Tibial Insert #3, 15mm
M-3301-1044	CR Tibial Insert #4, 15mm
M-3301-1045	CR Tibial Insert #5, 15mm
M-3301-1046	CR Tibial Insert #6, 15mm
M-3301-1050	CR Tibial Insert #0, 18mm*
M-3301-1051	CR Tibial Insert #1, 18mm
M-3301-1052	CR Tibial Insert #2, 18mm
M-3301-1053	CR Tibial Insert #3, 18mm
M-3301-1054	CR Tibial Insert #4, 18mm
M-3301-1055	CR Tibial Insert #5, 18mm
M-3301-1056	CR Tibial Insert #6, 18mm

UC Tibial Insert

Catalog Number	Description
M-3301-4010	UC Tibial Insert #0, 9mm*
M-3301-4011	UC Tibial Insert #1, 9mm
M-3301-4012	UC Tibial Insert #2, 9mm
M-3301-4013	UC Tibial Insert #3, 9mm
M-3301-4014	UC Tibial Insert #4, 9mm
M-3301-4015	UC Tibial Insert #5, 9mm
M-3301-4016	UC Tibial Insert #6, 9mm
M-3301-4020	UC Tibial Insert #0, 11mm*
M-3301-4021	UC Tibial Insert #1, 11mm

Implants

UC Tibial Insert Cont.

M-3301-4022	UC Tibial Insert #2, 11mm
M-3301-4023	UC Tibial Insert #3, 11mm
M-3301-4024	UC Tibial Insert #4, 11mm
M-3301-4025	UC Tibial Insert #5, 11mm
M-3301-4026	UC Tibial Insert #6, 11mm
M-3301-4030	UC Tibial Insert #0, 13mm*
M-3301-4031	UC Tibial Insert #1, 13mm
M-3301-4032	UC Tibial Insert #2, 13mm
M-3301-4033	UC Tibial Insert #3, 13mm
M-3301-4034	UC Tibial Insert #4, 13mm
M-3301-4035	UC Tibial Insert #5, 13mm
M-3301-4036	UC Tibial Insert #6, 13mm
M-3301-4040	UC Tibial Insert #0, 15mm*
M-3301-4041	UC Tibial Insert #1, 15mm
M-3301-4042	UC Tibial Insert #2, 15mm
M-3301-4043	UC Tibial Insert #3, 15mm
M-3301-4044	UC Tibial Insert #4, 15mm
M-3301-4045	UC Tibial Insert #5, 15mm
M-3301-4046	UC Tibial Insert #6, 15mm
M-3301-4050	UC Tibial Insert #0, 18mm*
M-3301-4051	UC Tibial Insert #1, 18mm
M-3301-4052	UC Tibial Insert #2, 18mm
M-3301-4053	UC Tibial Insert #3, 18mm
M-3301-4054	UC Tibial Insert #4, 18mm
M-3301-4055	UC Tibial Insert #5, 18mm
M-3301-4056	UC Tibial Insert #6, 18mm

PS Tibial Insert

Catalog Number	Description
M-3301-2010	PS Tibial Insert #0, 9mm*
M-3301-2011	PS Tibial Insert #1, 9mm
M-3301-2012	PS Tibial Insert #2, 9mm
M-3301-2013	PS Tibial Insert #3, 9mm
M-3301-2014	PS Tibial Insert #4, 9mm
M-3301-2015	PS Tibial Insert #5, 9mm

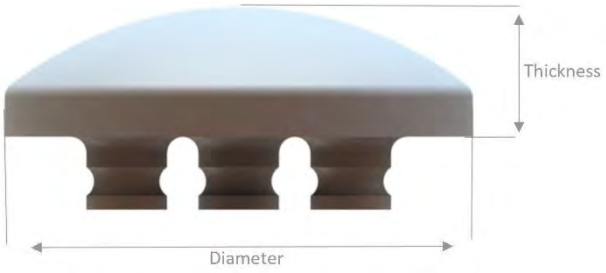
Implants

PS Tibial Insert Cont.

M-3301-2016	PS Tibial Insert #6, 9mm
M-3301-2020	PS Tibial Insert #0, 11mm*
M-3301-2021	PS Tibial Insert #1, 11mm
M-3301-2022	PS Tibial Insert #2, 11mm
M-3301-2023	PS Tibial Insert #3, 11mm
M-3301-2024	PS Tibial Insert #4, 11mm
M-3301-2025	PS Tibial Insert #5, 11mm
M-3301-2026	PS Tibial Insert #6, 11mm
M-3301-2030	PS Tibial Insert #0, 13mm*
M-3301-2031	PS Tibial Insert #1, 13mm
M-3301-2032	PS Tibial Insert #2, 13mm
M-3301-2033	PS Tibial Insert #3, 13mm
M-3301-2034	PS Tibial Insert #4, 13mm
M-3301-2035	PS Tibial Insert #5, 13mm
M-3301-2036	PS Tibial Insert #6, 13mm
M-3301-2040	PS Tibial Insert #0, 15mm*
M-3301-2041	PS Tibial Insert #1, 15mm
M-3301-2042	PS Tibial Insert #2, 15mm
M-3301-2043	PS Tibial Insert #3, 15mm
M-3301-2044	PS Tibial Insert #4, 15mm
M-3301-2045	PS Tibial Insert #5, 15mm
M-3301-2046	PS Tibial Insert #6, 15mm
M-3301-2050	PS Tibial Insert #0, 18mm*
M-3301-2051	PS Tibial Insert #1, 18mm
M-3301-2052	PS Tibial Insert #2, 18mm
M-3301-2053	PS Tibial Insert #3, 18mm
M-3301-2054	PS Tibial Insert #4, 18mm
M-3301-2055	PS Tibial Insert #5, 18mm
M-3301-2056	PS Tibial Insert #6, 18mm

Implants

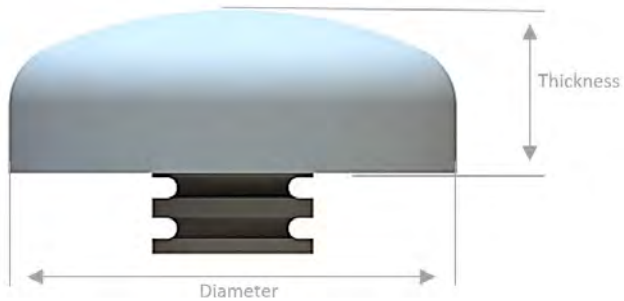
Patella- Onset



Catalog Number	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

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

Patella- Inset*



Catalog Number	Description
M-3402-0022	Patella 22mm*
M-3402-0025	Patella 25mm*
M-3402-0028	Patella 28mm*
M-3402-0032	Patella 32mm*
M-3402-0036	Patella 36mm*

Size	22mm	25mm	28mm	32mm	36mm
Diameter (mm)	22	25	28	32	36
Thickness (mm)	8	8	9	9	10

*Pending FDA Clearance

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STERIZO™

INSTRUMENT CATALOG

SXT-S-001 REV A DCR#
DC-0043
Effective Date 11/27/2019

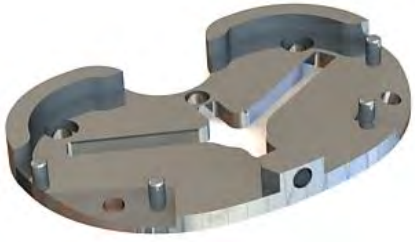
Instruments

Instrument Catalog

Femoral Trial

Catalog Number	Description
M-3111-1100	Femoral CR Trial Size 0 Left*
M-3111-1200	Femoral CR Trial Size 0 Right*
M-3111-1101	Femoral CR Trial Size 1 Left
M-3111-1201	Femoral CR Trial Size 1 Right
M-3111-1102	Femoral CR Trial Size 2 Left
M-3111-1202	Femoral CR Trial Size 2 Right
M-3111-1103	Femoral CR Trial Size 3 Left
M-3111-1203	Femoral CR Trial Size 3 Right
M-3111-1104	Femoral CR Trial Size 4 Left
M-3111-1204	Femoral CR Trial Size 4 Right
M-3111-1105	Femoral CR Trial Size 5 Left
M-3111-1205	Femoral CR Trial Size 5 Right
M-3111-1106	Femoral CR Trial Size 6 Left
M-3111-1107	Femoral CR Trial Size 6 Right
M-3111-2101	Femoral PS Trial Size 1 Left
M-3111-2201	Femoral PS Trial Size 1 Right
M-3111-2102	Femoral PS Trial Size 2 Left
M-3111-2202	Femoral PS Trial Size 2 Right
M-3111-2103	Femoral PS Trial Size 3 Left
M-3111-2203	Femoral PS Trial Size 3 Right
M-3111-2104	Femoral PS Trial Size 4 Left
M-3111-2204	Femoral PS Trial Size 4 Right
M-3111-2105	Femoral PS Trial Size 5 Left
M-3111-2205	Femoral PS Trial Size 5 Right
M-3111-2106	Femoral PS Trial Size 6 Left
M-3111-2107	Femoral PS Trial Size 6 Right

Tibial Tray Trial



Catalog Number	Description
M-3211-0000	Tibial Tray Trial Sz 0*
M-3211-0001	Tibial Tray Trial Sz 1
M-3211-0002	Tibial Tray Trial Sz 2
M-3211-0003	Tibial Tray Trial Sz 3
M-3211-0004	Tibial Tray Trial Sz 4
M-3211-0005	Tibial Tray Trial Sz 5
M-3211-0006	Tibial Tray Trial Sz 6

Instruments

CR Tibial Insert Trial

Catalog Number	Description
M-3311-1010	CR Tibial Insert Trial Size 0 - 9mm*
M-3311-1020	CR Tibial Insert Trial Size 0 - 11mm*
M-3311-1030	CR Tibial Insert Trial Size 0 - 13mm*
M-3311-1040	CR Tibial Insert Trial Size 0 - 15mm*
M-3311-1050	CR Tibial Insert Trial Size 0 - 18mm*
M-3311-1011	CR Tibial Insert Trial Size 1 - 9mm
M-3311-1021	CR Tibial Insert Trial Size 1 - 11mm
M-3311-1031	CR Tibial Insert Trial Size 1 - 13mm
M-3311-1041	CR Tibial Insert Trial Size 1 - 15mm
M-3311-1051	CR Tibial Insert Trial Size 1 - 18mm
M-3311-1012	CR Tibial Insert Trial Size 2 - 9mm
M-3311-1022	CR Tibial Insert Trial Size 2 - 11mm
M-3311-1032	CR Tibial Insert Trial Size 2 - 13mm
M-3311-1042	CR Tibial Insert Trial Size 2 - 15mm
M-3311-1052	CR Tibial Insert Trial Size 2 - 18mm
M-3311-1013	CR Tibial Insert Trial Size 3 - 9mm
M-3311-1023	CR Tibial Insert Trial Size 3 - 11mm
M-3311-1033	CR Tibial Insert Trial Size 3 - 13mm
M-3311-1043	CR Tibial Insert Trial Size 3 - 15mm
M-3311-1053	CR Tibial Insert Trial Size 3 - 18mm
M-3311-1014	CR Tibial Insert Trial Size 4 - 9mm
M-3311-1024	CR Tibial Insert Trial Size 4 - 11mm
M-3311-1034	CR Tibial Insert Trial Size 4 - 13mm
M-3311-1044	CR Tibial Insert Trial Size 4 - 15mm
M-3311-1054	CR Tibial Insert Trial Size 4 - 18mm
M-3311-1015	CR Tibial Insert Trial Size 5 - 9mm
M-3311-1025	CR Tibial Insert Trial Size 5 - 11mm
M-3311-1035	CR Tibial Insert Trial Size 5 - 13mm
M-3311-1045	CR Tibial Insert Trial Size 5 - 15mm
M-3311-1055	CR Tibial Insert Trial Size 5 - 18mm
M-3311-1016	CR Tibial Insert Trial Size 6 - 9mm
M-3311-1026	CR Tibial Insert Trial Size 6 - 11mm
M-3311-1036	CR Tibial Insert Trial Size 6 - 13mm
M-3311-1046	CR Tibial Insert Trial Size 6 - 15mm
M-3311-1056	CR Tibial Insert Trial Size 6 - 18mm

Instruments

UC Tibial Insert Trial

Catalog Number	Description
M-3311-4010	UC Tibial Insert Trial Size 0 - 9mm*
M-3311-4020	UC Tibial Insert Trial Size 0 - 11mm*
M-3311-4030	UC Tibial Insert Trial Size 0 - 13mm*
M-3311-4040	UC Tibial Insert Trial Size 0 - 15mm*
M-3311-4050	UC Tibial Insert Trial Size 0 - 18mm*
M-3311-4011	UC Tibial Insert Trial Size 1 - 9mm
M-3311-4021	UC Tibial Insert Trial Size 1 - 11mm
M-3311-4031	UC Tibial Insert Trial Size 1 - 13mm
M-3311-4041	UC Tibial Insert Trial Size 1 - 15mm
M-3311-4051	UC Tibial Insert Trial Size 1 - 18mm
M-3311-4012	UC Tibial Insert Trial Size 2 - 9mm
M-3311-4022	UC Tibial Insert Trial Size 2 - 11mm
M-3311-4032	UC Tibial Insert Trial Size 2 - 13mm
M-3311-4042	UC Tibial Insert Trial Size 2 - 15mm
M-3311-4052	UC Tibial Insert Trial Size 2 - 18mm
M-3311-4013	UC Tibial Insert Trial Size 3 - 9mm
M-3311-4023	UC Tibial Insert Trial Size 3 - 11mm
M-3311-4033	UC Tibial Insert Trial Size 3 - 13mm
M-3311-4043	UC Tibial Insert Trial Size 3 - 15mm
M-3311-4053	UC Tibial Insert Trial Size 3 - 18mm
M-3311-4014	UC Tibial Insert Trial Size 4 - 9mm
M-3311-4024	UC Tibial Insert Trial Size 4 - 11mm
M-3311-4034	UC Tibial Insert Trial Size 4 - 13mm
M-3311-4044	UC Tibial Insert Trial Size 4 - 15mm
M-3311-4054	UC Tibial Insert Trial Size 4 - 18mm
M-3311-4015	UC Tibial Insert Trial Size 5 - 9mm
M-3311-4025	UC Tibial Insert Trial Size 5 - 11mm
M-3311-4035	UC Tibial Insert Trial Size 5 - 13mm
M-3311-4045	UC Tibial Insert Trial Size 5 - 15mm
M-3311-4055	UC Tibial Insert Trial Size 5 - 18mm
M-3311-4016	UC Tibial Insert Trial Size 6 - 9mm
M-3311-4026	UC Tibial Insert Trial Size 6 - 11mm
M-3311-4036	UC Tibial Insert Trial Size 6 - 13mm
M-3311-4046	UC Tibial Insert Trial Size 6 - 15mm
M-3311-4056	UC Tibial Insert Trial Size 6 - 18mm

Instruments

PS Tibial Insert Trial

Catalog Number	Description
M-3311-2010	PS Tibial Insert Trial Size 0 9mm*
M-3311-2020	PS Tibial Insert Trial Size 0 11mm*
M-3311-2030	PS Tibial Insert Trial Size 0 13mm*
M-3311-2040	PS Tibial Insert Trial Size 0 15mm*
M-3311-2050	PS Tibial Insert Trial Size 0 18mm*
M-3311-2011	PS Tibial Insert Trial Size 1 9mm
M-3311-2021	PS Tibial Insert Trial Size 1 11mm
M-3311-2031	PS Tibial Insert Trial Size 1 13mm
M-3311-2041	PS Tibial Insert Trial Size 1 15mm
M-3311-2051	PS Tibial Insert Trial Size 1 18mm
M-3311-2012	PS Tibial Insert Trial Size 2 9mm
M-3311-2022	PS Tibial Insert Trial Size 2 11mm
M-3311-2032	PS Tibial Insert Trial Size 2 13mm
M-3311-2042	PS Tibial Insert Trial Size 2 15mm
M-3311-2052	PS Tibial Insert Trial Size 2 18mm
M-3311-2013	PS Tibial Insert Trial Size 3 9mm
M-3311-2023	PS Tibial Insert Trial Size 3 11mm
M-3311-2033	PS Tibial Insert Trial Size 3 13mm
M-3311-2043	PS Tibial Insert Trial Size 3 15mm
M-3311-2053	PS Tibial Insert Trial Size 3 18mm
M-3311-2014	PS Tibial Insert Trial Size 4 9mm
M-3311-2024	PS Tibial Insert Trial Size 4 11mm
M-3311-2034	PS Tibial Insert Trial Size 4 13mm
M-3311-2044	PS Tibial Insert Trial Size 4 15mm
M-3311-2054	PS Tibial Insert Trial Size 4 18mm
M-3311-2015	PS Tibial Insert Trial Size 5 9mm
M-3311-2025	PS Tibial Insert Trial Size 5 11mm
M-3311-2035	PS Tibial Insert Trial Size 5 13mm
M-3311-2045	PS Tibial Insert Trial Size 5 15mm
M-3311-2055	PS Tibial Insert Trial Size 5 18mm
M-3311-2016	PS Tibial Insert Trial Size 6 9mm
M-3311-2026	PS Tibial Insert Trial Size 6 11mm
M-3311-2036	PS Tibial Insert Trial Size 6 13mm
M-3311-2046	PS Tibial Insert Trial Size 6 15mm
M-3311-2056	PS Tibial Insert Trial Size 6 18mm

*Pending FDA Clearance

Instruments

Catalog Number	Description
M-3411-0060	Small Patellar Trial 29mm
M-3411-0070	Medium Patellar Trial 32mm
M-3411-0080	Large Patellar Trial 35mm
M-3411-0090	Extra-Large Patellar Trial 38mm
M-3411-0100	XXL Patellar Trial 41mm

Catalog Number	Description
M-3120-5000	Three Step Drill

Catalog Number	Description
M-3120-5001	Femoral IM Rod

Catalog Number	Description
M-3120-5002	Femoral IM Alignment Guide

Catalog Number	Description
M-3120-5003	Long Pin

Catalog Number	Description
M-3120-5004	Quick Pin Driver

Instruments

Catalog Number	Description
M-3120-5005	Distal Femoral Alignment Guide

Catalog Number	Description
M-3120-5006	Distal Femoral Cutting Block

Catalog Number	Description
M-3120-5007	Pin Extractor

Catalog Number	Description
M-3120-5008	Femoral Sizer Anterior
M-3120-5009	Femoral Sizer Posterior

Catalog Number	Description
M-3120-5010-0	Femoral A/P Chamfer Cutting Block Sz 0*
M-3120-5010	Femoral A/P Chamfer Cutting Block Sz 1
M-3120-5011	Femoral A/P Chamfer Cutting Block Sz 2
M-3120-5012	Femoral A/P Chamfer Cutting Block Sz 3
M-3120-5013	Femoral A/P Chamfer Cutting Block Sz 4
M-3120-5014	Femoral A/P Chamfer Cutting Block Sz 5
M-3120-5015	Femoral A/P Chamfer Cutting Block Sz 6

*Pending FDA Clearance

Instruments

Catalog Number	Description
M-3120-5016	Blade Gauge

Catalog Number	Description
M-3120-5017-0	PS Notch Cutting Block Sz 0*
M-3120-5017	PS Notch Cutting Block Sz 1
M-3120-5018	PS Notch Cutting Block Sz 2
M-3120-5019	PS Notch Cutting Block Sz 3
M-3120-5020	PS Notch Cutting Block Sz 4
M-3120-5021	PS Notch Cutting Block Sz 5
M-3120-5022	PS Notch Cutting Block Sz 6

Catalog Number	Description
M-3120-5023	Modular PS Reamer

Catalog Number	Description
M-3120-5024	PS Punch**

Catalog Number	Description
M-3120-5025	Femoral Driver**

Instruments

Catalog Number	Description
M-3120-5026	Femoral Impactor

Catalog Number	Description
M-3120-5027	Patellar Drill

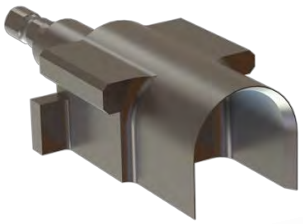
Catalog Number	Description
M-3120-5028	Alignment Rod

Catalog Number	Description
M-3120-5030	PS Notch Inserter**

Catalog Number	Description
M-3120-5050	Modular Femoral Driver

Catalog Number	Description
M-3120-5051	Modular PS Notch Inserter

Instruments



Catalog Number	Description
M-3120-5052	Modular PS Punch Broach

Catalog Number	Description
M-3120-5054	CR Drill

Catalog Number	Description
M-3220-5000	Tibial Cutting Block Left
M-3220-5001	Tibial Cutting Block Right

Catalog Number	Description
M-3220-5002	Tibial EM Guide

Catalog Number	Description
M-3220-5003	Tibial IM Guide

Instruments

Catalog Number	Description
M-3220-5004	Tibial Stylus

Catalog Number	Description
M-3220-5005	Slaphammer

Catalog Number	Description
M-3220-5006	Gap Gauge

Catalog Number	Description
M-3220-5007	Gap Gauge Insert 11mm
M-3220-5008	Gap Gauge Insert 13mm
M-3220-5009	Gap Gauge Insert 15mm
M-3220-5010	Gap Gauge Insert 18mm

Catalog Number	Description
M-3220-5011	Tibial Baseplate Trial Handle

Instruments

Catalog Number	Description
M-3220-5012	Removable Keel Punch Handle**

Catalog Number	Description
M-3220-5013	Keel Cutting Edge**

Catalog Number	Description
M-3220-5014	Tibial Baseplate Impactor**

Catalog Number	Description
M-3220-5015	Headed Pin

Catalog Number	Description
M-3220-5019	Tibial Broach Guide

Instruments

Catalog Number	Description
M-3220-5053	Modular Tibial Baseplate Impactor

Catalog Number	Description
M-3220-5054	Modular Tibial Insert Impactor

Catalog Number	Description
M-3220-5055	Tibial Keel Broach

Catalog Number	Description
M-3320-5000	Tibial Insert Impactor**

Catalog Number	Description
M-3420-5000	Patellar Resection Clamp

Instruments

Catalog Number	Description
M-3420-5001	Patellar Drill and Cement Clamp

Catalog Number	Description
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-3420-5007-0	Patellar Drill Guide 41mm

Catalog Number	Description
M-3420-5003	Patellar Cement Clamp

Catalog Number	Description
M-3420-5008	Vernier Caliper

Catalog Number	Description
G90100	Modular Handle

Notes:

Notes:

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STERIZO™

SAFETY INFORMATION

SXT-S-001 REV A DCR#
DC-0043
Effective Date 11/27/2019

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, 1565 N Central Expy Suite 220, Richardson, TX 75080 (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 270º F (132ºC)
Exposure Time 15 minutes
Drying time 55 minutes

PRE-VACUUMED STERILIZER (HI-VAC)
Double Wrapped in a FDA cleared 1-ply wrap
Temperature 270º F (132ºC)
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, Inc., 1565 N Central Expressway Suite 220, Richardson, TX 75080

Fuse Medical, Inc.
1565 N Central Expressway; Suite 220
Richardson, TX 75080
P: 469-862-3030
F: 469-862-3035
www.fusemedical.com

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